PB87-104774

Guidance for the Reregistration of Pesticide Products Containing Captafol as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

28 Sep 84

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB87 104774/AS
4. Title and Subtitle Guidance for the Reregistration of Pesticide Products Containing CAPTAFOL as the Active Ingredient.			5. Report Date Issued SEPT. 84
			6.
7. Author(s) EPA, Office of Pesticide Programs, Registration Division			8. Performing Organization Rept. No. 540/RS-86- 163
9. Performing Organization Name and Address US Environmental Protection Agency Office of Pesticide Programs Registration Division TS-767C 401 M Street, SW Washington, D. C. 20460			10. Project/Task/Work Unit No.
			11. Contract(C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address Same as #9			13. Type of Report & Period Covered
			14.
15. Supplementary Notes			

16. Abstract (Limit: 200 words)

This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manufacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement Publicly Available	19. Security Class (This Report) Unclassified	21. No. of Pages 129
	20. Security Class (This Page) Unclassified	22. Price

(See ANSI–Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4–77)
(Formerly NTIS–35)
Department of Commerce

540/RS-86-163

PB87-104774

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

CAPTAFOL

AS THE ACTIVE INGREDIENT

EPA CASE NUMBER 116

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460
September 28, 1984

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL
INFORMATION SERVICE
SPRINGFIELD, VA. 22161

TABLE OF CONTENTS

Page

Introduction 1

I. Regulatory Position and Rationale 4

II. Requirement for Submission of Generic Data 35a

III. Requirement for Submission of Product-Specific data 59

IV. Submission of Revised Labeling and Packaging Information . . 64

A. Label Contents 64

1. Product Name 64
2. Company Name and Address 64
3. Net Contents 64
4. Product Registration Number 65
5. Producing Establishment Registration Number 65
6A Ingredient Statement 65
6B Pounds Per Gallon Statement 65
7. Front Panel Precautionary Statements 65
7A Child Hazard Warning Statements 66
7B Signal Word 66
7C Skull and Crossbones and Word Poison 66
7D Statement of Practical Treatment 66
7E Referral Statement 66
8. Side/Back Panel Precautionary Labeling 66
8A Hazard to Humans and Domestic Animals 67
8B Environmental Hazard 67
8C Physical or Chemical Hazard 67
9 Misuse Statement 68
10A Storage and Disposal Block 68
10B Directions for Use 68

B. Collateral Information 68

V. Instructions for Submission 69

APPENDICES

Page

II-1 Bibliography (Including Guide for Use 70

II-2 FIFRA §3(c)(2)(B) Summary Sheet - EPA Form 8580-1 85

II-3 Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data, EPA Form 8580-6 . . 86

III-1 Product Specific Data Report 87

IV-1 Labeling Requirements and Use Classification (40 CFR §162.10 and 40 CFR §162.11) 88

IV-2 Table of Labeling Requirements and Sample Labels 97

IV-3 Physical/Chemical Hazards Labeling Statement 101

IV-4 Storage and Disposal Instructions 102

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g)directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this congressional mandate, EPA has established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necesssary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, § 3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time-frames outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Union Carbide Agricultural Products Co., Inc v. Ruckelshaus, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of section 3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in the Guidance Document which do not relate to compliance with the section 3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of a Notice of intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible unreasonable adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position of the Environmental Protection Agency (EPA) on cis-N-[1,1,2,2-tetrachloroethyl)thio]-4-cyclohexene-1,2-dicarboximide (captafol), based on an evaluation of the single registered manufacturing-use product (MUP), and certain end-use products (EUPs) containing captafol as the sole ingredient. Labeling requirements, tolerances, special local needs registrations authorized by Section 24c of the FIFRA, as well as registrations under Section 3 of FIFRA were considered in this analysis. The Agency sets forth the data requirements that must be met to register or reregister products covered by this Standard.

This Standard addresses registration requirements for current and future MUPs and labeling requirements for EUPs. Captafol MUPs that differ appreciably from the one described here may require amendments to this Standard. Also, use-patterns that differ from those described here may also require amendments to this Standard.

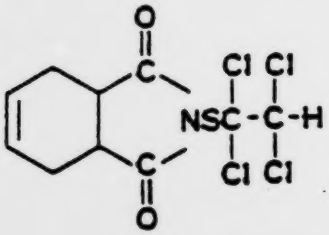
B. DESCRIPTION OF CHEMICAL

Captafol is the acceptable common name for cis-N-[(1,1,2,2-tetrachloroethyl)thio]-4-cyclohexene-1,2-dicarboximide and is recognized by the American National Standards Institute. Trade names for captafol are Difolatan and Folcid. Other names include Haipen, Merpafol Ortho 5865, Sanspor and Sulfemmide.

There is only one (1) EPA registered captafol MUP that may be used in the manufacturing of end-use pesticide products. The Office of Pesticide Programs Internal Control Number (EPA Shaughnessy Number) for captafol is 081701, and its CAS Number is 2425-06-1.

Captafol has the following identifying characteristics:

Empirical Formula: $C_{10}H_9Cl_4NO_2S$
Molecular Weight: 349.1
Structural Formula:



Color: White

Physical state: Crystalline solid

Odor: Slightly characeristic fumigant odor.

Melting Point: 159-161°C (162°C, pure compound)

Solubility: Insoluble in water, very low solubility in aliphatic hydrocarbon solvents. At 77°C, soluble at 2.5 g/100 ml in isopropanol; at 24°C, soluble at 42.8 g/100 ml in toluene.

Stability: Stable under environmental conditions. Decomposes slowly at melting point. Very slight hydrolytic decomposition in acid or neutral pH at ambient temperature. Strong sodium and potassium hydroxide solutions may cause spontaneous ignition of concentrate forms. In neutral or weakly basic solution, captafol slowly decomposes, the rate depending upon pH and temperature, being very slow below 7.0 and rapid above 9.0.

Captafol is a broad spectrum fungicide which is registered with the EPA for use in the control of foliar diseases of fruits and vegetables. It is also registered for application to foliage of peanuts, seeds of corn, cotton, peanuts, rice, and sorghum, to pineapple planting stock as a preplant treatment and to wood as a preservative. End-use products (EUPs) that have captafol as an active ingredient may be applied as either a spray or as a dust. As a wood preservative it is applied as an aqueous suspension under pressure. Captafol may be applied in combination with other fungicides and insecticides but not with oil sprays or alkaline products such as hydrated lime.

Captafol fungicidal activity is resistant to ultraviolet radiation. In tests with selected fungi, exposure to ultraviolet radiation for 18 hours did not significantly effect its fungicidal activity (W. D. Thomas, Phytopathology: Vol 56: 151-152). In field tests captafol had an average persistence on 12 plant species of 5.6 weeks (D. Neely, Phytophathology: Vol. 60: 1583-1586).

Laboratory studies have demonstrated that captafol may move across plant cuticle (Z. Sobel and L. V. Edgington, Phytopathology: Vol. 63: 505-510).

Captafol is manufactured as a 97% technical solely by Chevron Chemical Company. It is in 16 EPA registered products under Section 3 of FIFRA as amended September 30, 1978, and in 19 products under 24 (c) of the Act. These products range from 25 to 80 percent wettable powders, from 35 to 65 percent dusts, and as 27 or 39 percent flowable. There is also an 80.0 % water dispersible granular formulation.

C. REGULATORY POSITION AND RATIONALE

Based on a review and evaluation of all available data and other relevant information on captafol, the Agency has made the following determinations:

1. Captafol is placed under Special Review because it has oncogenic potential and is very highly toxic to fish. A Notice announcing the Agency's decision to initiate a Special Review will be published in the Federal Register. The Agency will not consider for re-registration any currently registered product containing captafol as a sole active ingredient until the Special Review has been concluded. However, currently registered products will remain registered while the Special Review is in process.

Rationale: Captafol has met the risk criterion for oncogenicity in §162.11 (a) of Title 40 (CFR). Toxicology studies have shown that captafol has an oncogenic potential in rats and mice. Dietary exposure to captafol has induced dose-related tumors in mice and rats.

Captafol is "very highly toxic" to fish (96-hour LC_{50} for rainbow trout is 21 parts per billion (ppb)). Reports of fish kills involving application to cranberries identified hazards to non-target organisms (criteria are met or exceeded as specified in §162.11 (3) (ii) (C) and §162.11 (3) (i) (3)). Under registered use patterns, after direct application to a 6-inch layer of water, the use of captafol may result in a maximum calculated concentration of more that 1/2 the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed (as measured on test animals specified in the Registration Guidelines). Application rates could result in 2,200 ppb to 9,190 ppb in 1/2 acre foot of water, thus the criteria may be exceeded. Hence, Special Review is necessary to fully evaluate and determine the extent of the risk involved.

2. Captafol is hereby classified as a "Restricted Use" pesticide; therefore, it is only for sale to and use by Certified Applicators or persons under the direct supervision of a Certified Applicator.

Rationale: Based on surrogate data, risk estimates indicate that an unreasonable risk may exist for farm workers exposed to captafol while mixing and/or loading and applying captafol. Dietary risk may exist for the general population via consumption of agricultural commodities treated with captafol. To reduce the risk while the Special Review is in process, the Agency is imposing certain interim measures by restricting captafol use and requiring label amendments.

3. The Agency is requiring that certain data be submitted on an expedited basis. These data include the following:

   a. Residue Chemistry data as specified in the data tables under §158.125.
   b. Environmental Chemistry as specified in the data tables under §158.130.
   c. Toxicology as specified in the data tables under §158.135.
   d. Toxicology exposure data as specified in the data tables under §158.130.

Rationale: The Agency is concerned about captafol's oncogenic potential and needs the data mentioned above to complete the Special Review. In addition, in reference to residue chemistry data, a review of these data indicate that the data are inadequate to support registration of seed, seed-piece and other plant propagule uses as non-food and non-feed uses. Data requirements to support these uses are listed in Table A and B.

The available environmental fate data are insufficient to fully assess the potential for exposure of humans and non-target organisms to captafol. When the required studies under §158.130 are submitted, a complete environmental exposure assessment can be made.

4. An interim 24-hour reentry interval has been imposed for the agricultural uses of captafol until adequate data have been submitted as specified in Table A, Section 158.130, Subpart K, Re-entry.

   Rationale: Captafol meets the criteria of 40 CFR, Section 158.140. Yet, there are no data to estimate reentry exposure to workers entering areas treated with captafol. Given that captafol has oncogenic potential, the Agency has set an interim time interval of 24 hours to caution any worker from reentering the treated areas without protective clothing. The data gap requires the submission of captafol reentry data in accordance with 40 CFR Parts 158.140 (Reentry Protection Data Requirements). When data are submitted, the Agency will reevaluate this restriction.

5. The Agency is requiring the following studies:
   a. Environmental Chemistry data as specified in the data tables - under §158.130.
   b. Product Chemistry data as specified in the data tables under §158.120.

   Rationale: There are inadequate data to conclude that captafol is not a ground water problem. Metabolites and degradates in soil have not been adequately studied. Mobility and the fate of the metabolites and degradates are required on an expedited basis. The Agency is concerned about surface water and the possible ground water contamination by captafol. In order to characterize the potential for captafol to enter ground water, the Agency needs the studies mentioned above. For example, the available product chemistry data are insufficient to fully assess the chemical at this time. When the required chemistry tests under §158.20 are submitted, a complete product chemistry evaluation can be made.

6. Acute toxicity studies on estuarine and marine organisms are required under this Standard. Data from fish early life stage studies, aquatic invertebrate life cycle studies, aquatic organisms accumulation and simulated or actual field testing with aquatic organisms may be required for Special Review pending results from environmental fate studies. Both the needed environmental fate data and the above mentioned data are to be submitted on a expedited basis.

Rationale: The Agency is concerned about the fish toxicity and toxic effects to estuarine and marine organisms, because captafol is very highly toxic to fish. The available environmental fate data are insufficient to fully assess the potential for exposure of humans and non-target organisms to captafol. When the required studies under 40 CFR §158.130 are submitted, a complete environmental exposure assessment can be made.

There are insufficient data to characterize the acute and chronic toxic effects of captafol on aquatic invertebrates. Toxicity data are needed for assessing the hazards to aquatic invertebrates.

7. Product labeling must be revised to include a statement concerning tumors, a requirement to use protective clothing and a restricted use statement. In addition, all end-use products intended for crop use, except seed uses and plant propagule treatments, must bear labeling restrictions for crop rotation and for reentering treated areas. (Refer to Section F, Required Labeling.)

   Rationale: To reduce risk from captafol's oncogenic potential and its toxicity to fish, and to maintain existing registrations, registrants must take certain interim measures by revising product labeling as specified in Section F.

8. Manufacturing-use pesticide products containing captafol as a sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the tables, in order to maintain existing registrations or to permit new captafol registrations.

   Rationale: Under FIFRA, the Agency cannot cancel or withhold registration simply because data are missing or inadequate (see Section 3(c)(2)(b) and 3(c)(7) of FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs and sets a timetable for generation of needed data. These data will be reviewed and evaluated when they are received and the Agency will determine at that time if they will affect the registration of captafol products.

D. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

All products that contain captafol as the sole active ingredient are subject to this standard and must bear required labeling and either comply with the acute toxicity limits, product composition, and use patterns requirements listed in Section E of this document, or submit data and a justification to amend the standard to encompass such products.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

Technical grade products must contain at least 97.0 percent captafol as the sole active ingredient. Each manufacturing-use product must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use captafol products must be substantially similar to that in the currently registered technical product. Any manufacturing-use product not meeting these requirements will be considered a new product and will require an amendment to the standard.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing captafol for acute toxicity category I, provided that the labeling of those products bear appropriate precautionary statements.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing captafol may be labeled for formulation only into end-use products for use as a fungicide for foliar applications to fruits, vegetables and peanuts, to seeds of corn, cotton, peanuts, rice, sorghum, to pineapple planting stock as a preplant treatment, and to wood as a preservative.

4. Labeling of Existing Stocks

All captafol product labeling must reflect the required labeling as specified under Section F (which follows) within six months after the date of this Standard.

F. REQUIRED LABELING

All technical grade and manufacturing-use products and end-use product (EUP's) must bear appropriate labeling as specified below and in 40 CFR §162.10. Other portions of this guidance package contain specific information regarding labeling requirements. Required labeling must be submitted within 90 days from the date of receipt of this Standard.

1. Precautionary statements to be used on labeling of all end-use captafol products:

   a. All end-use product labels must reflect the following statements: RESTRICTED USE PESTICIDE. For retail sale to, and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. "This product is classified as a "Restricted Use Pesticide because it contains captafol which has been determined to cause tumors in laboratory animals."
   Exposure to captafol during mixing, loading, and application may be hazardous to your health.
   This product contains captafol which has been determined to cause tumors in laboratory animals.

   b. All end-use products must have the labeling claim under "Direction for Use": "Wear impervious gloves, full body clothing during handling and application.

   c. All end-use products intended for crop use, except seed, seed piece, and plant propagule treatments must bear the following use restrictions:

      i Do not rotate treated crop with crops other than those with registered captafol uses.

      ii Do not allow persons to enter treated areas within 24 hours following application unless protective clothing is worn. Conspicuously post reentry information at site of application.

      iii Do not use captafol-treated rice seed in fields subsequently to be used for agricultural crops other than those with with registerd captafol uses.

      iiii Water from cranberry bogs, wetland taro fields (foliarly treated with captafol) and rice fields planted with captafol-treated rice seed must not be used for irrigation of crops other than those with registered captafol uses.

2. For end use products that bear labeling for use in greenhouses:

   a. Only the applicator is permitted to be in the greenhouse during application of captafol to soil. Open vents to greenhouse during application and at least 1 hour after application.

b. Workers planting in captafol treated soil in greenhouse must wear impervious gloves and full body clothing.

3. All products, manufacturing-use and end-use must bear the labeling precautionary statements:

DANGER
Causes irreversible eye damage. Harmful if swallowed or inhaled. May cause allergic skin reactions. Do not get in eyes. Wear goggles or face shield when handling. Avoid contact with skin and clothing. Remove and separately launder clothing before reuse.
This product contains captafol which has been determined to cause tumors in laboratory animals.

In addition, the following specific environmental hazard labeling requirements apply to either technical, manufacturing-use and end-use product as indicated.

a. All technical and MUP's must bear the following precautionary statements:

> This pesticide is extremely toxic to fish. Do not discharge into lakes, streams, ponds, or public waters unless in accordance with NPDES permit. For guidance contact your Regional Office of the Environmental Protection Agency. Do not discharge effluent containing cptafol into sewage systems without obtaining permission from the sewage treatment authority.

b. All EUP's that allow foliar applications except foliar applications to cranberries must bear the hazard precaution:

> This pesticide is extremely toxic to fish. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

c. All EUP's that allow foliar application to cranberries must bear the following environmental hazard precautions:

> This pesticide is extremely toxic to fish. Fish may be killed at recommendated application rates. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

d. All EUP's that allow seed treatment must bear the following environmental hazard precaution:

> This pesticide is extremely toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes.

4. Both MUP's and EUP's may need special labeling to protect endangered species. This will be determined after the required environmental chemistry data are reviewed, and in conjunction with EPA's evaluation of the potential risk of hazards to endangered species.

G. Tolerance Reassessment

1. Non-Seed Applications

The established tolerances for captafol are presently expressed as the fungicide captafol cis-N-[Cl,1,2,2-tetrachloroethyl)thio]-4-cyclohexene-1,2-dicarboximide without specifying the metabolites. The following metabolites have been identified in plants:

delta^4-tetrahdyrophthalimide (II), phthalimide (III), 4,5-epoxyhexahydrophthalimide (IV), 4,5-dihydroxyhexahydrophthalimide (V), 3,hydroxy-delta^4 tetrahydrophthalimide (VI), 5-hydroxy-delta^3-tetrahydrophthalimide (VII), delta^4 tetrahydrophthalamic acid (VIII), delta^4-tetrahydrophthalic acid (IX), and dichloroacetic acid (XIII).

The following table lists the present status for tolerances in parts per million for residues of captafol.

Raw Agricultural Commodity	Parts Per Million in Captafol Residues U.S.	 Canada	 Mexico	 Codex
Apples	0.25	0.1(N)	--	5.0
Apricots	30.0	0.5	--	15.0
Blueberries	35.0	--	--	--
Cherries, sour	50.0	10.0	--	10.0
Cherries, sweet	2.0	2.0	--	2.0
Citrus fruits	0.5	--	--	--
Corn, Fresh (sweet K+CWHR)	0.1(N)	--	--	--
Cranberries	8.0	--	--	8.0
Cucumbers	2.0	2.0	--	2.0
Madadamia nuts	0.1(N)	--	--	0.1(N)
Melons	5.0	2.0	--	2.0
Nectarines	2.0	--	--	--
Peanuts, hulls	2.0	--	--	--*
Peanuts, meats (hulls removed)	0.05	--	--	0.05
Onions	0.1(N)	0.1(N)	--	0.5
Peaches	30.0	15.0	--	15.0
Pineapples	0.1(N)	--	--	10.0
Plums (fresh prunes)	2.0	0.2	--	10.0
Potatoes	0.5	0.1(N)	--	0.5
Taro (corn)	0.02	--	--	--
Tomatoes	15.0	5.0	--	5.0
Carrots	--	--	--	0.5

*Codex MRL for whole peanuts is 0.5 ppm.

2. Seed Applications:

No tolerances have been established for captafol residues in or on any crop for which captafol is registered solely for seed treatment, because heretofore seed treatment uses have been considered to be nonfood uses. These crops include: corn (field), cotton, peanuts, rice, sorghum (grain and forage).

3. Plant Metabolism:

Available plant metabolism data are not adequate to support the established tolerances. Quantification and identification of captafol and its metabolites were performed in only two studies, in each case only 7 days after last treatment. One of the studies was with immature tomato plants. As indicated in Table A, additional data must be submitted to qualify and identify residues of captafol and its metabolites in three representative mature crops for which use of captafol is registered.

Future tolerances and existing tolerances must be amended to include delta^4-tetrahydrophthalimide (THPI). Results of the required plant metabolism studies may identify other metabolites of concern.

4. Animal Metabolism:

The metabolism of captafol in ruminants is adequately understood. The available data on metabolism of captafol in poultry is inadequate, and therefore residues in poultry eggs, fat, meat and meat by-products can not be assessed. As in Table A, additional data must be submitted.

5. Analytical Methods for Residues:

Adequate gas chromatography methods are available for studies on residues of captafol in or on raw agricultural commodities or processed food or feed commodities on which tolerances are established. Method trials as indicated in Table A must be conducted to evaluate methods to determine THPI, 3-OH THPI, and 5-OH THPI in animal products, and THPI in plant commodities.

6. Storage Stability:

The storage stability of captafol residues in or on animal and plant samples is not adequately understood. Data are needed on the stability of captafol and its tetrahydrophthalmide metabolite in representative crops, such as apples, cherries, citrus, potatoes, tomatoes and sweet corn, and in or on animal products (meat, milk, eggs) stored at subfreezing temperatures for intervals approximating the storage intervals of treated samples, in order to determine the magnitude of the residues.

7. Tolerances Needed to Allow Continued Registration of Uses:

a. Use in Propagation of Strawberry Plants

There are no available data to support a nonfood use classification for the use of captafol formulations on strawberries, i.e., it has not been demonstrated that no dectectable residues will be found in or on strawberries harvested from daughter plants which were produced from treated mother plants. Residues of the captafol metabolite THPI are readily absorbed by plants (refer to Nature of the Residue in Plants section). The metabolism of captafol in plants is not adequately understood. As a result, the captafol tolerance expression must be reevaluated upon receipt of the required plant metabolism data. If residues other than intact captafol and THPI are determined to be of concern, additional residue data for such metabolites in or on strawberries may be required.

The following data are required at the present time: Residues of captafol per se and its THPI metabolite in or on strawberries produced on daughter plants originating from propagating plants which were treated (in the propagation beds) at 7-day intervals beginning May 1 with the 4 lb/gal FIC formulation at 3 lb ai/A.

Upon receipt of the above data, a decision will be made as to the appropriateness of the nonfood classification of this use, and whether a tolerance is required. Alternatively, the registrant may cancel this 24(c) registration.

b. Use on Pear Trees as a Delayed Dormant to Green Tip Stages

An intrastate label has been issued by the state of New York (NY Reg. No. 038655-10453) for use of the 4 lb/gal FlC at 5 lb ai/100 gal during the delayed dormant to green tip stages.

Data are not available for the use of captafol formulations on pear trees nor has a tolerance been established for captafol residues in or on pears. A tolerance must be proposed and the necessary data submitted, or the intrastate label cancelled.

If the registrant wishes to maintain the active status of the intrastate label, then the following data must be submitted, as well as a tolerance proposal:

Residue of captafol per se and THPI in or ripe pears (or at the stage harvested for storage) following application of the 4 lb/gal FlC at 5 lb ai/100 gal during the green tip stage. The number of gallons applied per acre must be specified and must be conducted in New York. Alternatively, the label may be cancelled.

c. Use on Sugarcane Propagules.

A Florida state [24(c)] label for the 4 lb/gal FlC formulation (FL760012) is registered for seed-piece treatment at 500 ppm ai in water as a 20 minute dip or at 12,500 ppm ai in water as a spray.

Conclusions:

Seed treatments with captafol have been considered non-food uses. However, available plant metabolism data indicate that residues of captafol may be taken up into mature plants from treated seed. Therefore seed-piece treatments are uses for which residue data and tolerance proposals must be submitted. Captafol and its metabolite THPI are the residues of concern in plants; however, the nature of the residue in plants is not adequately understood. Should the required plant metabolism data indicate additional metabolites of concern, then additional data and tolerance proposals for these metabolites will be required. The following data are required:

Data reflecting residues of captafol and THPI in or on cane and forage grown from seed pieces sprayed with a 12,500 ppm ai water suspension of the 4 lb/gal FlC formulation. Forage must be collected at intervals throughout the growing season or until residues are no longer dectectable. This is necessary to determine appropriate pregrazing or prefeeding intervals. If detectable residues occur in mature cane, then processing studies must be completed to determine whether residues concentrate in molasses, refined sugar and bagasse. Tolerances must be proposed for cane and forage. Also, if residues concentrate in processed products, appropriate food/feed additive tolerances must be proposed. Tests must be conducted in sugarcane production areas of Florida.

Processing studies, if needed, should utilize cane bearing measurable weathered residues. The registrant may wish to propose label feeding and/or grazing restrictions in lieu of submitting residue data for forage.

d. Use as a Seed Treatment for Cotton, Field Corn, Rice and Sorghums

A 4 lb/gal EC formulation is registered for seed treatments to acid delinted cottonseed at 0.094 lb ai/100 lb of seed, machine delinted cottonseed at 0.141 lb ai/100 lb of seed, and to rice at 0.125-0.188 lb ai/100 lb of seed. A 70% WP formulation is registered for seed treatments to field corn at 0.47 oz ai/bushel or 0.875 Oz ai/100 lb of seed, and to sorghum at 2.1 ozs. ai/100 lb of seed.

Heretofore, seed treatments with captafol have been considered non-food uses. However, available plant metabolism data (refer to Nature of the Residue in Plants section) indicate that residues of captafol may be taken up into mature plants from treated seed. Therefore seed treatments are uses for which residue data and tolerance proposals must be submitted. The nature of the residue in plants is not adequately understood. If the required plant metabolism data indicate additional metabolites of concern, additional residue data and tolerance proposals for these metabolites will be required.

The following data are required: Data reflecting residues of captafol and THPI in or on cottonseed and forage grown from machine delinted seed treated with the 4 lb/gal FlC formulation at 0.141 lb ai/100 lb of seed, and from acid delinted seed treated at 0.094 lb ai/100 lb of seed.

Forage samples must be collected at intervals throughout the growing season or until residues are no longer detectable. This is necessary to determine appropriate pregrazing or prefeeding intervals. If detectable residues occur in seed, then processing studies must be completed to determine whether residues concentrate in meal, hulls, soapstock and crude and refined oil. Tolerances must be proposed for cottonseed and forage. Also, if residues concentrate in processed products, appropriate food/feed additive tolerances must be proposed. Test sites should include California and Texas which produced 22% and 38%, respectively, of the U.S. cottonseed crop in 1981 (preliminary figures; Agricultural Statistics, 1982, p. 114).

Data are required reflecting residues of captafol and THPI in or on field corn grain, forage, silage, and fodder grown from seed treated with the 70% WP formulation at 0.875 oz ai/100 lb of seed. Forage and silage samples must be collected at intervals throughout the growing season or until residues are no longer detectable. If detectable residues occur in grain, then processing studies must be completed to determine whether residues concentrate in milled products and crude and refined oil. Tolerances must be proposed for corn grain, forage, silage and fodder. Also, if residues concentrate in processed products, appropriate food additive tolerances must be proposed. Tests should be conducted in Illinois or Iowa which produced 13% or 17%, respectively, of the 1981 field corn crop (preliminary figures; Agricultural Statistics, 1982, p. 32).

Data are needed reflecting residues of captafol and THPI in or on rice grain and straw grown from seed treated with the 4 lb/gal EC formulation at 0.188 lb ai/100 lb of seed. If detectable residues occur in grain, then processing studies must be completed to determine whether residues concentrate in polished rice, hulls, or milled products. Tolerances must be proposed for rice grain and straw. Also, if residues concentrate in processed products, appropriate food/feed additive tolerances must be proposed. Tests should be conducted in Arizona and California which produced 37% and 23%, respectively, of the U.S. rice crop in 1981 (preliminary figures; Agricultural Statistics, 1982, p. 21).

Data are required reflecting residues of captafol and THPI in or on sorghum grain, forage, fodder, silage, and hay grown from seed treated with the 70% WP formulation at 2.1 oz ai/100 lb of seed. Forage, silage, and hay samples must be taken at intervals throughout the growing season or until residues are no longer detectable. If detectable residues occur in or on grain, then processing studies must be completed to determine whether residues concentrate in flour or milled products. Tolerances must be proposed for sorghum grain, forage, fodder, silage, and hay. Also, if residues concentrate in processed products, appropriate food additive tolerances must be proposed. Tests should be conducted in Kansas and Texas which produced 27% and 31%, respectively, of the U.S. sorghum corp in 1981 (preliminary figures; Agricultural Statistics, 1982, p. 52).

All processing studies should utilize raw agricultural commodities bearing measurable weathered residues. The registrant may wish to propose label feeding and/or grazing restrictions in lieu of submitting residue data for forage, fodder, silage, hay or straw.

e. Tolerance for Residues of Captafol in Meat, Milk, Poultry or Eggs.

The maximum expected dietary intake of residues of captafol by beef cattle would be 7.1 ppm if the diet consisted of 20% wet citrus pulp, 5% peanut hulls, 30% potato culls, 20% wet tomato pomace, and 25% dry tomato pomace should the pending tolerances (PP#7F1962/FAP#7H5166) for soybean hulls (3 ppm), hay (45 ppm) and forage (15 ppm) be established, the maximum expected intake would be 15 ppm based on a diet consisting of 5% peanut hulls, 20% wet tomato pomace, 25% dry tomato pomace, 20% soybean hulls, 10% soybean hay and 20% soybean forage. The maximum expected dietary intake of residues of captafol by dairy cattle would be 5.6 ppm if the diet consisted of 25% dehydrated citrus pulp, 10% wet citrus pulp, 30% cull potatoes, 10% wet tomato pomace, and 25% dry tomato pomace: should the pending tolerances for soybean hay and forage be established, the maximum intake would be 27 ppm based on a diet consisting of 20% dry tomato pomace, 40% soybean hay, and 40% soybean forage. The maximum expected dietary intake of residues of captafol by turkeys and broilers would be 0.5 ppm if the diet included 5% dehydrated apple pomace, 10% peanut meal, 5% peanut soapstock, 7% potato culls, and 3% wet tomato pomace. Should (after Special Review has been completed) the pending tolerance for soybeans (1 ppm) be established, the maxium expected intake would be 1.1 ppm based on a diet which includes 20% soybean seed, 30% soybean meal and 5% soybean soapstock in addition to the feed items listed above. The maximum expected dietary intake of residues of captafol by laying hens would be 0.4 ppm if the diet included 10% peanut meal, 5% peanut soapstock, 5% pineapple bran, 20% potato culls and 2% wet tomato pomace: should the pending tolerance for soybeans be established, the maximum expected intake would be 1.2 ppm based on a diet consisting of 3% pineapple bran, 20% potato culls, 2% wet tomato pomace, 50% soybean seed, 20% soybean meal, and 5% soybean soapstock. The maximum expected dietary intake of residues of captafol by swine is 1.8 ppm based on a diet consisting of 1% dyhydrated citrus pulp, 10% wet citrus pulp, 9% peanut meal, 20% pineapple bran, 50% potato culls and 10% wet tomato pomace; should the pending tolerances for soybeans and soybean hulls be established, the maximum expected intake would be 2.4 ppm if the diet consisted of 35% cull potatoes, 10% wet tomato pomace, 20% soybean seed, 20% soybean meal, 10% soybean hulls and 5% soybean soapstock.

The metabolism of captafol in ruminants (including milk) is adequately understood. The metabolism of captafol in poultry is not adequately understood due to the inadequacy of the available metabolism study. The established and pending tolerances for captafol per se must be changed to reflect combined residues of captafol and its metabolite THPI. It is likely that such actions will result in increases in the magnitude of established tolerances for feed items. Such tolerance level increases would result in corresponding increases in the maximum expected dietary intake of residues of concern (captafol and THPI) by cattle, poultry and swine.

The following data requirements are based on presently established tolerances for residues of captafol in feed items: however, the petitioner should note that if the feed item tolerances are altered in the future to include residues of the metabolite THPI, then feeding studies reflecting the transfer of THPI at maximum expected dietary levels to meat, milk, poultry and eggs will be required. In addition, establishment of the soybean tolerances would significantly increase required feeding levels. Since the metabolites of concern in poultry, eggs, meat, and milk have not been delineated at the present time, data are required reflecting residues of the parent and the metabolites THPI, PI, 3-OH THPI, and 5-OH THPI. The following data are required:

Cattle (> three cows/dosing level) must be dosed with 7, 21, and 70 ppm of captafol in the total diet until residues plateau in milk, or for 4 weeks if no residues are detected in milk. Milk must be sampled twice daily. Animals must be slaughtered within 24 hours of the final dose and residues (see above) determined in muscle, liver, kidney and fat as well as milk.

Poultry (>10 hens/dosing level) must be dosed with 0.5, 1.5, and 5 ppm of captafol in the total diet until residues plateau in eggs, or for 4 weeks if no residues are detected in eggs. Egg samples should be taken twice daily. Animals must be sacrificed within 24 hours of the final dose and residues (see above) determined in muscle, liver, fat, skin, and gizzard as well as eggs.

As the available metabolism studies (refer to Nature of the Residues in Animals) have shown that there is a reasonable expectation of residues in meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep, in milk of cattle and goats, and in meat, meat by-products and fat of poultry, category 3 of 40 CFR 180.6(a) does not apply. Thus tolerances must be proposed, based on the above-required data, for these animal products. In addition, should the required metabolism and/or residue data indicate a reasonable expectation of residues in eggs, then a tolerance proposal for eggs will also be required.

f. Regulatory Concern for Residues of Captafol[a]:

Residues of captafol have been detected in or on samples of domestic fish. This commodity does not currently have established tolerances for captafol residues. It is not known whether the residues of captafol in or on this commodity are due to illegal use of captafol products or contamination. Additional residue monitoring is required to determine the cause of these illegal residues.

8. Tolerance Reassessment Summary:

Sufficient data are available to determine that the currently established tolerances for residues of captafol in or on the following commodities are adequate: apricots, blueberries, cranberries, macadamia nuts, nectarines,

[a] The Agency is concerned about illegal residues in imported beans and imported strawberries and will consult with the FDA on this issue.

peaches, peanut hulls, and taro corms (40 CFR 180.267). However, additional data concerning residues of metabolite THPI must be submitted for the these commodities since the residues of concern in or on plants have recently been modified to include THPI. In addition to THPI data, other residue data are required to support the tolerances for captafol in or on the following commodities: apples, citrus fruits, corn (sweet), cucumbers, melons, onions, peanuts, pineapples, plums (prunes), potatoes, and tomatoes. THPI data and tolerance changes must be submitted for sweet and sour cherries. Residue data and tolerance proposals must be submitted for the following commodities: crops receiving only seed treatments (cotton, field corn, rice, and sorghum), pears (state label use only), strawberries [propagating bed use: Section 24(c)], sugarcane (seed piece use), and taro foliage. Tolerances for the following commodities are pending: carrots, coffee beans, pecans, soybeans, and soybean forage and hay. Plant metabolism of captafol is not adequately understood, therefore residues other than captafol and THPI may need to be sought if deemed to be of concern. The metabolites of concern in animal products are the parent compound, THPI, 3-OH THPI, and -OH THPI. Additional data are required for poultry metabolism. Also, feeding studies are required for ruminants and poultry. Additional storage stability data are necessary to validate the residue data. No crop group tolerances may be established based on the available data.

The TMRC is 1.4579 mg/day based on a 1.5-kg diet. The changes in the residue definition, the requested tolerance proposals and the pending tolerances noted above will all affect a change in the TMRC level. The data requirements to support established tolerances as listed in 40 CFR 180.267 are given in Table A.

The Maximum Permissible Intake (MPI) for a 60 kg person is 1.68 mg/day based on an Acceptable Daily Intake (ADI) of 0.028 mg/kg. The present TMRC represents 86.8% of the MPI. The inclusion of the major metabolite (THPI) in the tolerance expression may result in an increase in the TMRC and a greater percentage of the MPI utilized.

The ADI for captafol is based on a chronic toxicity study in rats. A NOEL was established at 56 ppm for non-oncogenic effects. In that study the next highest dose level caused cholangiectasis in liver, increase in hyperplasia of tubule epithelium, megalocytic cells and transtional cell hyperplasia in kidney, increased erosion/ulceration hyperkertosis/acanthosis, ground substance in glandular mucosa, and dilated pits in stomach. The reported dosage level was corrected from 75 ppm to 56 ppm based on the instability of captafol in the diet. In rat 56 ppm is approximately equivalent to 2.8 mg/kg. Using a safety factor of 100 and a NOEL of 2.8 mg/kg/day, the ADI would be 0.028 mg/kg for man. The only registrant of technical captafol, Chevron Chemical Company, has been requested to complete the histopathology examination of the low and mid-dose liver and mammary gland tissues; therefore, the NOEL may change. The NOEL of 56 ppm is for systemic effects excluding the issue of oncogenicity for which a risk assessment will be performed.

Use Pattern Statement

Captafol may only be used for formation into products intended for those uses listed in F.3 above. For more detailed use-pattern information on all registered uses of captafol (both single active and multiple active ingredient products) refer to the EPA Compendium of Registered Pesticides, Volume II: Fungicides and Nematicides, pp. C-09-95.01 to C-09-95.08 (Issue, Oct, 1974) and/or USDA Compilation of Registered Uses of Fungicides and Nematicides, pp. C-09-95.01 to C-09-95.11, (Issued Feb. 1, 1983), and /or EPA Index to Pesticide Chemicals for captafol (Issued: Sept. 24, 1981).

H. PRELIMINARY ANALYSIS OF CURRENT BENEFITS AND RISKS

1. Current Benefits Review

a. Introduction

The Agency has completed a preliminary review of benefits for the major use sites for captafol. The following information will be expanded during the Special Review.

b. Use Sites

Captafol is used as a non-systemic protectant fungicide that has a broad spectrum of activity. It has a high level of persistance on foliage and is apparently redistributed on leaf surfaces by rain. This persistence allows the growers of certain crops to choose between applications of captafol at minimum rates using frequent intervals or higher rates using less frequent intervals. It may be combined with commonly used fungicides and insecticides, with the exception of strongly alkaline materials and oil sprays.

Captafol is federally registered to control foliar diseases of certain fruits and vegetables. The major sites are citrus, potatoes, tomatoes, sweet corn, plums, watermelon, apples, and cherries; nearly half of the usage is for the last two crops. It is also federally registered for use on the seed of corn, cotton, peanut, rice, and sorghum; peanut foliage; cranberries; taro; pineapple planting stock; and in wood preserving.

Approximately 4.5 to 5 million pounds are used per year. Captafol is manufactured as a 97 percent technical by Chevron Chemical Company. Osmose Wood Preserving Company, Incorporated and the University of Hawaii, Cooperative Extension Service also hold federal registrations. Currently, 16 products are federally registered. There are 19 FIFRA section 24(c) registrations. Formulations include 25 to 80 percent wettable powders, 35 to 65 percent dusts, 27 or 39 percent flowable, and 80 percent water dispensible granules. The 39 percent flowable is the most widely used formulation for ground and aerial applications and is used for wood preservation and seed treatment.

c. Benefits on Apples

Captafol may only be applied to apples in the mid-western and eastern states. It is applied by ground equipment to control scab disease during the primary infection period. The primary infection period is from the dormant to the one-fourth green leaf stage of the apple tree. It is used as a single application spray in place of multiple applications of alternative fungicides. Captafol is applied generally by an airblast sprayer mounted on a truck or trailer. The spray volume will vary according to the size of the tree. Plant protection lasts until the blossom pink stage when using the 12 pounds active ingredient (lb. ai.) application rate per acre or through blossom petal fall using 20 lb. ai. per acre. Infections during the secondary infection period must be controlled by other fungicides because of captafol's potential phytotoxicity to fruit and leaves.

Captafol is used primarily in Michigan, New York, and Pennsylvania. Use information indicate no captafol usage in the western United States because labeling limits its use to eastern and midwestern apples. Several fungicides are used more extensively on apples than captafol in the Midwest and Northeast in terms of base acres treated and pounds active ingredient applied. A number of these other fungicides are applied to control various diseases that may or may not include scab.

Many registered alternatives are available. The most viable include dichlone, captan, metiram, folpet, glyodin, thiram, maneb, triforine, mancozeb, zineb, diammonium EBDC, and a combination of thiophanate-methyl or benomyl with another fungicide to which resistance has been not demonstrated. Up to five applications of any one of the alternatives must be made to control the primary stage infections accomplished by one application of captafol. Even though captafol is much more expensive per application than any of the other fungicides used on apples, the difference in cost is much lower when the number of applications required for the alternatives is taken into account. Since up to five applications may be needed, it may be more expensive than using captafol.

d. Benefits on Cherries

Usage for cherries is limited to those which are mechanically harvested because captafol may cause an allergic reaction in some individual hand harvestors. In addition, captafol may only be applied to sour cherries, with the exception of California and Oregon. It is most frequently applied in the northcentral and eastern regions of the United States and is registered for control of Coccomyces leaf spot, brown rot blossom blight, and fruit brown rot. For sour cherries it is applied using 3 to 9 lb. ai. per acre, depending on disease severity. For cherries in California and Oregon a rate of 2.4 to 4.8 lb. ai. per acre is used. Application is generally made using airblast sprayers.

For control of Coccomyces leaf spot disease, growers may choose a "seasonal program" or a "reduced application program." For the seasonal program, captafol may be applied at 0.5 to 1.0 lb. ai. in 100 gallons of water at 10 day intervals for three to four treatments beginning at petal fall. The application may be the same as those used for fruit brown rot. For the reduced application program captafol is applied once at petal fall using 3.0 lb. ai. in 100 gallons of water. This treatment may overlap one or more brown fruit rot treatments.

For brown rot blossom blight, captafol is applied using three to six applications at two to four day intervals starting at blossom development and continuing through petal fall. It may be applied at 1.0 lb. ai. in 100 gallons of water. In major sour cherry producing states such as Michigan and Oregon, generally 300 gallons and 400 gallons per acre, respectively, are used.

For fruit brown rot, captafol is applied at 0.5 to 1.0 lb. ai. in 100 gallons of water and is applied when conditions are favorable for disease development, such as extended periods of rain. The history of disease in an orchard is also considered. Four applications may be made at ten day intervals from petal fall and one application may be made after harvest.

With the exception of benomyl, captafol is the most expensive fungicide per acre of application. Despite its cost, it is still one of the most extensively used fungicides on cherries in the northcentral and eastern parts of the U.S. The most viable alternatives for these three diseases are dichlone, dodine, ziram, and benomyl used in combination with a fungicide against which resistance has not been demonstrated. Other viable alternatives are also available, depending on the disease. For brown rot blossom blight and fruit brown rot additional alternatives include captan, sulfur, and triforine. For leaf spot control glyodine, folpet, and zineb are available.

e. Benefits on Tomatoes

Captafol is limited for use on tomatoes which are mechanically harvested. Generally these tomatoes are destined for processing rather than fresh market. Captafol is registered for control of anthracnose, early blight, late blight, gray leaf spot, nailhead spot, Septoria leaf spot, and fruit rot. In California it is also registered for control of black mold. A rate of 1.2 to 16 lb. ai. per acre may be used. Row crop boom and airblast equipment, and airplane and helicopter airblast equipment may be used.

To control anthracnose captafol is generally applied using two applications 20 days apart. To control black mold captafol is mixed with 30 to 200 gallons of water per acre for ground application and 10 gallons per acre for aerial application. Application begins when fruits are well formed and continue at seven to ten day intervals for up to six applications. For control of the other diseases 30 to 150 gallons of water per acre are used for ground applications and 5 to 10 gallons per acres for aerial application. In Michigan the flowable formulation may be applied by center pivot or solid set irrigation equipment.

Despite captafol's high per acre application cost, it is still one of the most extensively used fungicides on tomatoes. In California and the north/northeastern United States, where most of the processed tomatoes are produced, captafol holds the second largest market share of base acres treated. Preliminary data indicate that captafol usage on tomatoes has declined slightly in the last two to three years.

Twenty-six alternative fungicides are registered for control of one or more of the diseases for which captafol is registered. The major ones include metiram, anilazine, captan, chlorothalonil, diammonium EBDC, folpet, maneb, nabam, metalaxyl combined with manozeb, and zineb. For the major diseases early blight, late blight, and anthracnose, metiram, anilazine, captan, chlorothalonil, diammonium EBDC, and maneb are the most viable.

2. Preliminary Risk Analysis for Oncogenicity

a. Oncogenicity Studies

A two year mouse study (Chevron Chemical Company, 1981, MRID 00088817) showed both compound and dose-related oncogenic lesions at the middle and high dose groups. These lesions included lymphosarcomas, myeloproliferative disease, harderian gland hyperplasia, benign harderian gland adenomas, and hemangiosarcomas. This compound also produced dose-related non-oncogenic lesions at all dose levels. The control group results were combined with those from a concurrently run study on another chemical. As a result the Agency classified this study as supplemental and is requiring that results for separate controls be submitted. However, the information was adequate to calculate a preliminary risk assessment assuming no neoplasms in the controls, which represents the worst case. There was a significant increase in mortality in the middle and high dose mice, frequently accompanied by neoplastic lesions. This preliminary assessment does not take these early deaths-with-tumors into account. When the Agency receives the additional control data, a time-to-tumor assessment will be conducted.

A two year rat feeding study (Hazelton Laboratories, 1983, GS0122044) was also conducted and showed a dose-related increased incidence of fibroadenomas of the mammary gland and an increased incidence of neoplastic nodules in the liver of females. Not all the animals at the middle and low doses were subjected to histopathological examination so that the numbers may not be representative.

A histopathological examination of the previously unexamined female liver and mammary gland tissues at the middle and low doses is required. The information will be included in the risk assessment conducted during the Special Review. This preliminary assessment is based on the results for the high dose and controls only.

Captafol has oncogenic potential. The Agency has determined that captafol meets or exceeds the risk criterion for oncogenicity in 40 CFR § 162.11(a).

The Agency's Interim Cancer Assessment Guidelines (41 FR 21402) state that when the Agency judges a chemical to be a potential human carcinogen, the Agency must estimate its possible impact on public health at current and anticipated levels of exposure. The Agency recognizes that the available techniques for assessing the magnitude of cancer risk to human populations based on animal data are crude. Uncertainties in the extrapolation of dose response data to very low dose levels occur. Also, animals and humans have varying levels of susceptibility. Thus, these estimates should be viewed as a health hazard index that reflects the degree of oncogenic activity and human exposure to captafol.

b. Exposure Analysis and Risk Estimates

1) Non-dietary

The Agency based the applicator exposure analysis on surrogate data for pesticides with similiar use patterns, label directions, and use patterns. Applicator exposure for fruit, citrus, vegetable, pineapple planting stock, seed treatment, and wood preservation application were calculated. An exposure study on captafol was recently submitted. If valid, the information will be used to revise the risk assessment.

For vegetables, fruit, and citrus, the use rates for captafol are quite variable, depending on the desired number of applications and the particular requirements for controlling fungal diseases. The Agency used 2 lb. ai. per acre for ground application. Captafol is applied to citrus and fruit using airblast equipment and to vegetables using ground boom and aerial equipment. For aerial application, more concentrated

A two year rat feeding study (Hazelton Laboratories, 1983, GS0122044) was also conducted and showed a dose-related increased incidence of fibroadenomas of the mammary gland and an increased incidence of neoplastic nodules in the liver of females. Not all the animals at the middle and low doses were subjected to histopathological examination so that the numbers may not be representative.

A histopathological examination of the previously unexamined female liver and mammary gland tissues at the middle and low doses is required. The information will be included in the risk assessment conducted during the Special Review. This preliminary assessment is based on the results for the high dose and controls only.

Captafol has oncogenic potential. The Agency has determined that captafol meets or exceeds the risk criterion for oncogenicity in 40 CFR § 162.11(a).

The Agency's Interim Cancer Assessment Guidelines (41 FR 21402) state that when the Agency judges a chemical to be a potential human carcinogen, the Agency must estimate its possible impact on public health at current and anticipated levels of exposure. The Agency recognizes that the available techniques for assessing the magnitude of cancer risk to human populations based on animal data are crude. Uncertainties in the extrapolation of dose response data to very low dose levels occur. Also, animals and humans have varying levels of susceptibility. Thus, these estimates should be viewed as a health hazard index that reflects the degree of oncogenic activity and human exposure to captafol.

b. Exposure Analysis and Risk Estimates

1) Non-dietary

The Agency based the applicator exposure analysis on surrogate data for pesticides with similiar use patterns, label directions, and use patterns. Applicator exposure for fruit, citrus, vegetable, pineapple planting stock, seed treatment, and wood preservation application were calculated. An exposure study on captafol was recently submitted. If valid, the information will be used to revise the risk assessment.

For vegetables, fruit, and citrus, the use rates for captafol are quite variable, depending on the desired number of applications and the particular requirements for controlling fungal diseases. The Agency used 2 lb. ai. per acre for ground application. Captafol is applied to citrus and fruit using airblast equipment and to vegetables using ground boom and aerial equipment. For aerial application, more concentrated suspensions are applied. Generally eight applications are made per season with the exception of the use pattern for sweet corn, which is treated with 16 applications per season.

For pineapple planting stock, the planting stock is tank dipped in a 1.5 percent suspension at planting and then planted by hand. Captafol is used to coat seeds using a commercial seed treating apparatus. It is undiluted and in dry form and applied usually at a rate of 2 ounces ai. per 100 pounds of seed.

The emulsifiable liquid concentrate formulation is registered as a wood preservative for use with chromated copper arsenate. A 0.02 to 0.04 percent ai. solution is used.

The dermal airblast, inhalation airblast, and ground boom application were based on surrogate data from many pesticides (J. C. Reinert and D. J. Severn, (?), GS0122055; J. Davis, 1978, GS0122054; and Versar, Inc., 1984, GS0122057, respectively). Aerial, dip, and seed application were based on captan (J. Jensen, 1982, GS0122056) and wood preservative estimates on Position Document 2/3 on Wood Preservatives (US EPA, 1980, GS01220058).

The Agency used the following assumptions to calculate exposure to captafol:

i) The mixer/loader or applicator weighs 60 kg.

ii) Neither the mixer/loader nor applicator wears protective clothing during application. According to label directions before this Guidance Document was issued, no protective clothing was required except for one formulation.

iii) The Agency assumes 100 percent dermal penetration. A dermal penetration study was recently submitted and is being reviewed. If valid, the information will be used to revise the risk assessment.

iv) The Agency assumes a breathing rate of 1.2 cubic meters per hour for applicators.

v) Application to pineapples assumes no inhalation or dermal exposure because captafol is applied mechanically as a dip and no such exposure results.

vi) Application to pineapples assumes dermal contact twice a day with 6 ml of treatment suspension while planting seed pieces over 120 planting days per year. No inhalation exposure results because planting is done outdoors.

vii) Application to sweet corn assumes no inhalation because no inhalation exposure results to the applicator with aerial application.

viii) Aerial application did not consider exposure for flagmen because they are rarely used. Mechanical flagging is the prevalent practice.

ix) The seed treatment use combines mixing/loading and applying because they are done at the same time.

x) The wood preservative use assumes no inhalation exposure. The captafol formulation does not require mixing, and its application is usually metered in with a remote pumping system. Its use is in conjunction with chromated copper arsentate (CCA) wood preservative solutions at ambient temperatures. This use is also under presssure in an enclosed treatment cylinder. If added by hand, the mixer/loader (applicator) has minimal opportunity for inhalation exposure. Also, the excess treatment solution is usually pumped back into a storage tank minimizing any significant captafol exposure except for the wood surface. Although captafol may have a vapor pressure, as opposed to CCA salt solutions with no vapor pressure, most treatment facilities and the subsequent stacking and drying is done outside, not in enclosed spaces.

xi) The wood preservative use assumes the mixer/loader (applicator) accidentally comes in contact with 6 ml of 30 percent concentrate each day.

The following Table 1 summarizes the exposure for a mixer/loader and applicator in various use situations:

Table 1--ESTIMATION OF EXPOSURE FOR CAPTAFOL USAGE DURING MIXING/LOADING AND APPLICATION

Use	mg/hr	hr/day	hr/yr	mg/kg/day	mg/kg/yr
			MIXING LOADING		
Airblast					
Inhalation	5.9	0.5	4	0.05	0.4
Dermal	181	0.5	4	1.5	12
Ground Boom					
Inhalation	7.8	0.5	4	0.06	0.5
Dermal	282	0.5	4	2.4	20
Pineapple Dip					
Inhalation	0.82	0.5	60	0.007	0.84
Dermal	7.68	0.5	60	0.06	7
Aerial--Sweet Corn					
Inhalation	2	0.5	8	0.02	0.3
Dermal	500	0.5	8	4	64
Seed Treatment					
Inhalation	0.82	0.25	0.75	0.003	0.01
Dermal	7.68	0.25	0.75	0.03	0.1
Wood Preservative					
Inhalation	-	-	-	-	-
Dermal	2340	0.5	50	39	3900
			APPLICATION		
Airblast					
Inhalation	0.06	4	32	0.004	0.03
Dermal	26	4	32	2	13
Ground Boom					
Inhalation	1	4	32	0.07	0.6
Dermal	18.6	4	32	1.2	10
Pineapple Dip					
Inhalation	-	-	-	-	-
Dermal	180	7.5	9.0	3	360
Aerial--Sweet Corn					
Inhalation	-	-	-	-	-
Dermal	2.3	1	16	0.4	0.6

The preliminary risk estimates representing the worst case is based on the incidence of neoplastic liver lesions in rats and lymphosarcomas in mice. The extrapolation linearized multi-stage model was used, and estimates were based on 40 working years over a life span of 70 years. The estimates which resulted for mixer/loader and applicator combined ranged from 3 x 10^{-2} to 2 x 10^{-6}, with 5 x 10^{-4} for the major use sites.

2) Dietary

The estimates of dietary exposure to pesticide residues in the diet are a function of several factors. These factors include (1) the residues remaining in or on the commodity; (2) the percentage of the commodity in the daily diet of 1.5 kilograms; and (3) 60 kilogram body weight. The residues are measured in parts per million, and human exposure to pesticide residues in a commodity is measured in terms of milligrams of pesticide per kilogram of body weight per day.

The Agency's dietary estimates assume a uniform distribution of treated crops among the U.S. population and an average daily consumption of those crops by individuals. Although an individual's exposure could vary considerably depending on eating habits and geographic location, the values are considered representative for the total U.S. population over a lifetime.

The Agency calculated worst case dietary exposure based on the same multi-stage model and incidence of tumors. This exposure was based on the TMRC, which assumes residues are at 100 percent of the tolerance levels. The actual dietary exposure may be lower. The TMRC of 1.46 mg/day is equivalent to 0.02 mg/kg/day for a 60 kg person. This results in a preliminary oncogenicity risk estimate of 2 x 10^{-4}.

3. Preliminary Risk Assessment for Ecological Effects

a. Ecological Effects Studies

The Agency reviewed several valid ecological effects studies, which characterize captafol as very highly toxic to fish. The results of these studies are summarized in Table 2.

This page is left blank for future amendments and revisions.

Table 2--ACUTE TOXICITY STUDIES FOR FISH

Species	Results for 96-hour LC_{50} in parts per billion	Citation (MRID)
	USING TECHNICAL FORMULATIONS	
Lepomis macrochius (Bluegill sunfish)	158 (137 - 180.9)	U.S. EPA, 1980, GS0122036
Lepomis macrochius (Bluegill sunfish)	45 (35.78 - 56.60)	U.S. EPA, 1976, GS0122037
Lepomis macrochius (Bluegill sunfish)	212 (150 - 600)	U.S. EPA, 1980, GS0122038
Lepomis macrochius (Bluegill sunfish)	230 (180 - 320)	Thompson et al., 1980, 00069607
Salmo gairdneri (Rainbow trout)	27 (23.81 - 40.48)	U.S. EPA, 1976, GS0122034
Salmo gairdneri (Rainbow trout)	190 (161.4 - 223.8)	U.S. EPA, 1980, GS0122033
	USING FORMULATED PRODUCT	
Carassius auratus (Goldlife)	178 (146 - 217)	Johnson and Finley, 1980, 00003503
Ictalurus punctatus Channel catfish	28	same
Lepomis macrochius (Bluegill sunfish)	59	same
Salmo gairdneri Rainbow trout)	21	same

b. Risk Assessment

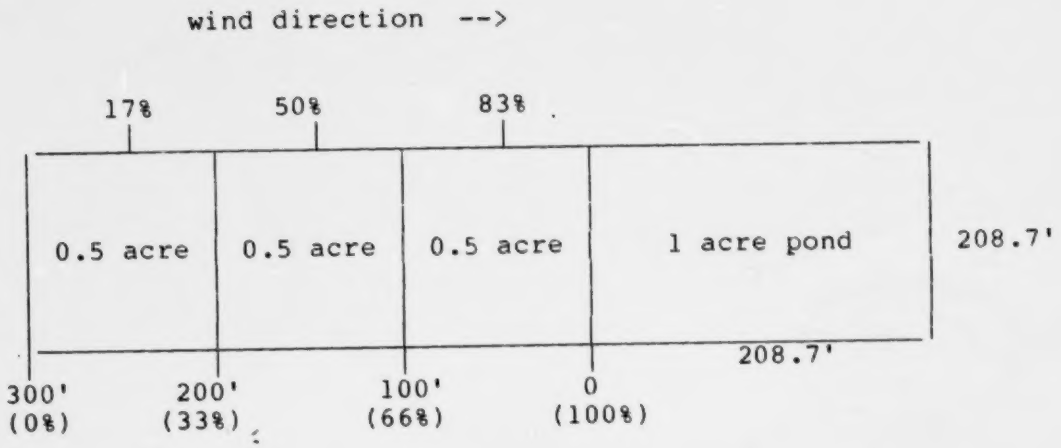
The Agency is concerned about the effect of captafol on fish as a result of drift and/or run-off during application to cranberries, orchards, and tomatoes. The Agency is also looking into captafol's effect on endangered species.

Biological monitoring studies (R. W. Felthousen, 1977, GS0122059 and GS0122060) in New Jersey resulted in fish kills after the application of captafol at 5 lb. ai. per acre. There is a possibility that the entire fish population was eliminated in one bog. It cannot be directly proven that the fish kill resulted from the captafol application because residue studies were not done. However, captafol is very highly toxic to fish, and the fish kill occurred shortly after application. The Agency is also aware that cranberry bogs may be irrigated by sprinkler systems or by flooding, which would increase the possibility of a future fish kills. Because many bogs border viable waters, aerial applications would also increase the chance of fish exposure to captafol from drift.

The Agency is concerned about the use of captafol in orchards based on the two incidents in cranberries and based on current use practices. In Florida the recommended application rate to citrus is 16 to 20 lb. ai. per acre. The label states that captafol be used only in orchards with overhead irrigation, which assures that the fungicide is distributed to the new leaves and fruit. This may result in runoff and is of concern because many groves are located near or on estuaries.

The Agency has estimated possible aquatic environmental concentrations. Generally citrus is sprayed using airblast equipment to achieve proper penetration and coverage. From 100 to 2,000 gallons of water per acre are used. Multiple applications are not recommended at the higher dosage rates.

The following spray drift model assesses the spray drift impact on a graduated basis. (This diagram is not to scale). This model assumes normal wind under average conditions.



This model assumes that captafol is sprayed over an area 0 to 300 feet from a one acre pond. This area is divided into 100 foot intervals consisting of 0.5 acres. The wind is blowing from the application site towards the pond. Under normal circumstances approximately 40 percent of the spray will not hit the target. One-half of this off-target spray can be expected to volatize, which results in 20 percent of the material remaining. This material will drift towards the one acre pond. The model assumes that the amount of material drifting will decrease 33 percent with each 100 foot interval. The percentages from each 100 foot interval were averaged to determine the percentage of pesticide available for drift, which are 83%, 50%, and 17%. Following is a sample calculation of the amount of drift entering the pond, assuming 20 lb. ai. are applied.

20 lb. ai. x 20% x 0.5 acres x 83% = 1.66 lb.
20 lb. ai. x 20% x 0.5 acres x 50% = 1.0 lb.
20 lb. ai. x 20% x 0.5 acres x 17% = 0.34 lb.

1.66 + 1.0 + 0.34 = 2.90 lb.

The amount entering the pond spreads throughout the pond, which is six feet deep. The expected residues in the pond are 180 parts per billion (ppb) and exceeds the LC_{50}.

An estuary is represented using one-half acre foot of water. The expected residues using the same procedure and application rate results in 2,200 ppb, which also exceeds the LC_{50}.

The Agency also estimated the impact of runoff. The runoff model assumes the a six acre-feet pond (one acre large and six feet deep) and has a drainage of ten acres with one percent of the application rate entering the water. At the 20 lb. ai. application rate, the expected residues would be two pounds or 122 ppb. The fish LC_{50} values are approached or exceeded.

The results of these estimates meet or exceed the Special Review criterion specified in 40 CFR §§ 162.11(3)(ii)(C) and 162.11(3)(i)(B)(3).

The Agency also is concerned about the use of captafol on tomatoes. In certain areas, growers use a plastic cover to keep weeds down, hasten maturity through heat retention, retain soil fumigants, and to shed rain. Too much rain causes the fruit to split or develop soft spots, which detracts from the overall quality of the product. When plastic is used, it covers two feet on each side of the center, or four out of every six feet are covered with plastic. Irrigation is used on all tomatoes in California, as well as in other areas. The result of using plastic and irrigation may create a hazard to fish because of run-off from the plastic into the irrigation system and into associated waters.

With regard to the protection of endangered species from the use of captafol, the Agency has prepared a request for a formal consultation with the Office of Endangered Species, U.S. Fish and Wildlife Service, U.S. Department of the Interior on September 26, 1984 (as required by Section 7 of the Endangered Species Act of 1973, as amended).

This assessment is preliminary in nature and will be refined during the Special Review process, when additional environmental fate and ecological effects data can be included.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

---

1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

---

*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B	Yes	GS 0122046	No
81-2 - Acute Dermal Toxicity	TGAI	A,B	Yes	GS 0122046	No
81-3 - Acute Inhalation Toxicity -Rat	TGAI	A,B	No	-	Yes (6 months)
81-7 - Acute Delayed Neurotoxicity - Hen [9]	TGAI	-	-	-	-
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B	Partially	00093672 (Rodent)	Yes (Non-rodent) (18 months)
82-2 - 21-Day Dermal [9]	TGAI	-	-	-	-
82-3 - 90-Day Dermal [9]	TGAI	-	-	-	-
82-4 - 90-Day Inhalation - Rat	TGAI	A,B	No	-	Yes (18 months)
82-5 - 90-Day Neurotoxicity-Hen/Mammal [9]	TGAI	-	-	-	-

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A,B	Partially	GS 0122044 (rodent)	Yes (non-rodent) (36 months) (rodent)[10]
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A,B	Partially	GS 0122044 (rat)[4] 00088817 (mouse)[4]	Yes [10] [11]
83-3 - Teratogenicity - 2 species	TGAI	A,B	Partially	05001994 [5] GS 0122042 (rat) GS 0122045 (rabbit)[7] GS 0122048 (rabbit)[7]	Yes[6] (12 months)
83-4 - Reproduction, 2-generation	TGAI	A,B	Yes	GS 0122043	No
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B	Partially	GS 0122040 00046435	Yes[8] (12 months)
84-2 - Chromosomal Aberration	TGAI	A,B	Yes	GS 0122040 / 0122047 GS 0122046/ 00027544	No
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B	Yes	GS 0122041	No

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A,B	Yes	00061996 00096902	No
85-2 - Domestic Animal Safety [9]	Choice	-	-	-	-
85-3 - Dermal Absorption	TGAI	A,B	No	-	Yes (6 months)[a]

a/ A dermal absorption study was received by EPA (July 17, 1984): at the time of the issuance of this Standard the study was under Agency review.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

§158.135 Toxicology
(continued)

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than indicated in Table A.

4/ These studies have been classified as supplementary and need additional information from the registrant in order to determine if they may be used to satisfy the data requirement.

5/ This study has been classified as supplementary and a study is needed to clarify the equivocal results.

6/ A study in hamsters using two test groups, one dosed on day 7, and the other dosed on day 8 of gestation, is needed.

7/ This recently submitted study is currently under review.

8/ A gene mutation test in mammalian cells in culture with and without metabolic activation or utilizing cells with metabolically competent cells.

9/ This test is not required.

10/ Additional histopathology is needed for GS 0122044, chronic rat study.

11/ Additional information is needed for 00088817, mouse oncogenicity study.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition[b]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
EPA REG. NO. 239-2230 (97%T)[a]				
§158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Diclosure of Ingredients	TGAI	Yes	GS0122030	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	GS0122032	Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	Partially	GS0122028, GS0122030	Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	GS0122029	No
63-3 - Physical State	TGAI	Yes	GS0122029	No
63-4 - Odor	TGAI	Yes	GS0122029	No
63-5 - Melting Point	TGAI	Yes	GS0122029	No
63-6 - Boiling Point	N/A[d]	N/A		No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		No

---

[a] The 97% technical (T) also serves as a manufacturing-use product.

[b] Composition: TGAI = technical grade of the active ingredient: PAI = pure active ingredient.

[c] Data must be submitted no later than 6 months from the date of this Standard.

[d] Not required because the 97% technical is a solid at room temperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition[b]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
EPA REG. NO. 239-2230 (97%T)[a]				
§158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI or PAI	Partially	GS0122051	Yes
63-9 - Vapor Pressure	PAI	No		Yes
63-10 - Dissociation Constant	PAI	No		Yes
63-11 - Octanol/ Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	Yes	GS0122050	No
other Requirement:				
64-1 - Submittal of Samples	N/A	N/A		No

---

a The 97% technical (T) also serves as a manufacturing-use product.
b Composition: TGAI = technical grade of the active ingredient: PAI = pure active ingredient.
c Data must be submitted no later than 6 months from the date of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	See Footnote A	Yes[3]
- Livestock	PAIRA and plant metabolites	Partially	See Footnote B	Yes[4]
171-4 - Residue Analytical Method				
- Plant residues	Pure Analytical Standards and metabolites	Partially	See Footnote C	Yes[5]
- Animal residues Presently there are no established tolerances	Pure Analytical Standard and metabolites	Partially	See Footnote C	Yes[6]
171-4 - Storage Stability Data	PAI	Partially	00091274	Yes[7]

A. Bibliographic Citations: 00025129, 00025130, 0009619, 00096916, 00072884, 0081808 and 05003661.

B. Bibliographic Citations: 00096829, 00096830, 00025952, 00025119, 00025120, 00025124, 00025127, 00061996, 00053240 and 00096902.

C. Bibliographic Citations: 00096847, 00096848, 00096843, 00091215, 00091214, 0052318, 0031709, 00025123, 00096911, 00025123 and 00025133
GS0122001, GS0122002, GS0122003, GS0122004, GS0122005, GS0122006, GS0122052
GS0122053

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residues Studies for Each Food Use				
Citrus Fruit Group[g]				
Citrus Fruits	EP	Partially	GS0122012	Yes[12]
Pome Fruits Group[h]				
Apples	EP	Partially	GS0122007	Yes[8]
Pears	EP	None		Yes
Stone Fruits Group[i]				
Apricots	EP	Partially	GS0122008 GS0122009 GS0122010	yes[9]
Cherries, Sour and Sweet	EP	Partially	00096828 and GS0122011	Yes[11]
Nectarines	EP	Partially	Same as for Apricots	Yes[18]
Peaches	EP	Partially	Same as for Apricots	Yes[21]
Plums (Fresh Prunes)	EP	Partially	GS0122021	Yes[23]
Small Fruit and Berries Group[j]				
Blueberries	EP	Partially	00096889 and GS0122014	Yes[10]
Cranberries	EP	Partially		Yes[14]
Strawberries	EP	None		Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residues Studies for Each Food Use				
Tree Nuts Group[k] Macadamia Nuts Pecan Nutmeats (Shells removed) (Pending)	EP	Partially	GS0122015	Yes[16]
Cereal Grains Group[l] Corn, fresh (including sweet, kernels plus cobs with husks removed)	EP	Partially	GS0122013	Yes[13]
Other Raw Agricultural Commodities Coffee beans (green) (Pending)				
Peanuts, meats (hulls removed)	EP	Partially	GS0122017 GS0122018	Yes[19]
Peanuts, hulls	EP	Partially	Same as for Peanuts Meats	Yes[19]
Pineapples	EP	Partially	GS0122020	Yes[22]
Sugarcane	EP	None		Yes
Taro (corm)	EP	Partially	GS0122025	Yes[25]

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/]
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue-Residues Studies for Each Food Use				
Root and Tuber Vegetable Group[a]				
Carrots (Pending)				
Potatoes	EP	Partially	GS0122022 GS0122023 GS0122050	Yes[24]
Bulb Vegetable Group[b]				
Onions	EP	Partially	GS0122019	Yes[20]
Legume Vegetable (Succulent or Dried) Group[c]				
Soybeans (Pending)				
Foliage of Legume Vegetable Group[d]				
Soybean Forage and Hay (Pending				
Fruiting Vegetables (Except Cucurbits Group[e]				
Tomatoes	EP	Partially	GS0122025 GS0122026 GS0122027	yes[26]
Cucurbit Vegetable Group[f]				
Cucumbers	EP	Partially	00096817	Yes[15]
Melons	EP	Partially	GS0122016	Yes[17]

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

§158.125 Residue Chemistry (continued)

a. Residue data are required for two additional members of eht group (radish and sugar beet). Note that data in support of a proposed tolerance for captafol residues in or on carrots are currently under review.

b. Residue data are required for one additional member of this crop group (garlic, leek or shallot).

c. Residue data are required for the three representative commodities of this group: beans (one succulent and one dried variety); peas (one succulent and one dried variety) and soybeans; captafol formulations are currently not registered for use on any member of this crop group (use on soybeans has been proposed.

d. Same as c above.

e. Residue data are required for one additional member of this group (peppers). IR4, Rutgers University PP No. OE2365 (099439) submitted data pertaining to residues of captafol *per se* in or on peppers; however the data will not satisfy group tolerance requirements because no data pertaining to residues of THPI were submitted.

f. Residue data are needed for an additional representative member of this crop group (summer squash). Currently, captafol formulations are registered for use only on cucumbers and melons.

g. A tolerance of 0.5 ppm has been established for the residues of captafol in or on citrus fruits. Additional data are required to fully support this group tolerance.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

§158.125 Residue Chemistry (continued)

h. A crop group tolerance is not appropriate, as additional data are required for the representative commodities apples and pears. A tolerance has been established for apples but not for pears.

i. A crop group tolerance is not appropriate because the tolerances established for members of this crop group differ by more than a factor of five (2-50 ppm). Data are required in support of established tolerances for representative crops.

j. Crop group tolerance is not appropriate because residue data on captafol *per se* and its THPI metabolite are required for a *Rubus* spp., grape, strawberries, blueberries and cranberries. Also, the established PHI for blueberries (21 days) differ significantly from that of cranberries (50 days).

k. A crop group tolerance is not appropriate because residue data for three representative commodities (almond, pecan and English walnut) are required. Residue data have been submitted for almond, but no data on the THPI metabolite were submitted. A petition to establish a tolerance for residues of captafol *per se* in or on pecans (PP No. 6F1795) is currently under review.

l. A crop group tolerance is not appropriate because: 1. Additional data are required to support the established tolerance for fresh corn, 2. Registered uses on field corn, sorghum and rice (seed treatment only) differ significantly from uses on sweet corn (seed treatment in ID and FL and multiple foliar applications in FL; 3. Residue data and tolerance proposals are required for rice, sorghum, and field corn; 4. Residue data are required for one additional member of this crop group (wheat).

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

§158.125 Residue Chemistry (continued)

1/ Composition: TGAI = Technical grade of the active ingredient: PAIRA = Pure active ingredient, radiolabeled: TEP = Typical end-use product: EP = End-use product.

2/ Data must be submitted no later than 12 months from the date of receipt of this Standard.

3/ The metabolism of captafol in plants is not adequately understood due to the lack of sufficient data on this topic. The following additional data are required:

The uptake, distribution, and metabolism of carbonyl-labeled $[^{14}C]$captafol in representative crops, preferably a tree fruit, potatoes, tomatoes and corn following foliar and soil applications. Sampling intervals through at least 21 days post-treatmeent must be included. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate the terminal residues. Residue identities must be confirmed by a method such as GC, HPLC, and/or mass spectrometry.

4/ Presently, the metabolism of captafol [cis-N-[(1,2,2-tetrachloroethyl)thio]-4-cyclohexene-1,2-dicarboximide(I)] in ruminants is adequately understood. However, the available data for poultry metabolism of captafol are inadequate; thus the residues of concern in poultry and eggs cannot be ascertained. The following additional data are required:

Poultry (laying hens) must be dosed with carbonyl-labeled $[^{14}C]$captafol daily for at least 3 days. Residues must be characterized in tissues (including muscle, liver, kidney, fat, heart, gizzard, and skin) and eggs. Animals must be sacrificed within 24 hours of the last ^{14}C-dose (eggs should be collected twice daily). Animals should not be preconditioned with unlabeled material. Identification of ^{14}C-metabolites should be confirmed by some alternative method, such as GC or MS.

5/ Method trials must be conducted to evaluate methods determining THPI, 3-OH THPI, and 5-OH THPI in animal products and THPI in plant commodities. For confirmatory purposes, the TLC procedures in method RM-6 (submitted under PP#5G0453(114470)] are adequate as are existing GC procedures with column substitutions.

6/ Same as 5 above.

7/ The storage stability of captafol residues in or on animal and plant samples is not adequately understood. The following additional data are required:

Data demonstrating the stability of captafol and its tertrahydropthalamide (THPI) metabolites in or on representative crops (such as apples, cherries, citrus, potatoes, tomatoes, and sweet corn) and animal products (meat, milk, and eggs) stored at subfreezing temperatures for intervals approximating the storage intervals of treated samples used to determine the magnitude of the residue.

8/ Apples. Residue data involving levels of captafol per se and its THPI metabolite in or on apples following delayed or dormant spray application using either the 4 lb/gal FlC or 80% WDG formulation at 20 lb ai/A from tests conducted in midwestern states.

9/ Apricots. Residue data from apricots treated with twice with dormant applications of the 80% WP at 6.4 ai/A, once in the fall and again in early spring at bud swell. Captafol and THPI residues should be determined separately for fruit samples taken at their normal time of harvest. The studies should be conducted in CA, UT, and WA. Note that other metabolites may need to be sought if the requested plant metabolism studies reveal the presence of other residues of concern.

10/ Blueberries. Residues of captafol and its THPI metobolites in or on mature blueberries following multiple treatment with the 4 lb/gal FlC or 80% WDG at 4 lb ai/A. Applications should begin at the early green tip stage and continue at 1-week intervals throughout petal fall after which application should continue at 10-day intervals until 21 days prior to harvest. Tests should be conducted in ME, MI, and NJ.

Residue data for captafol and THPI (analyzed and reported separately) from sour cherries harvested at their normal time of maturity after being subjected to the following treatment regime: (i) four foliar treatments during the blooming period (treatments spaced 2 days apart, ending at petal fall) with the 4 lb/gal FlC sprayed to runoff at 1 lb ai/100 gal until normal fruit maturity. The studies should take place in MI (65.4%), NY (6.2%) and OR (3.7%); percentages of U.S. sour cherry production contributed by states shown parenthetically.

11/ Residue data for captafol and THPI (analyzed and reported separately) from sweet cherries harvested at normal maturity after four foliar treatments during the blooming period (treatments spaced 4-7 days apart, ending at petal fall) with the 80% WP or the 4 lb/gal FlC sprayed to runoff at 1.6 lb ai/100 gal (400 gal spray/A). The studies should take place in CA or OR.

In addition, since the metabolism of captafol in plants is not adequately understood (see Nature of the Residue in Plants section), data for additional metabolites of captafol may be required if the requested studies discover residues of concern other than captafol and THPI.

12/ Residue data from orange products (dried pulb, peel, oil, molasses, juice) processed from whole oranges bearing measurable, weathered residues. Exaggerated rates of applications only may be required to obtain such initial residues. Captafol and THPI should be quantified separately.

Residue data concerning oranges (in FL) treated from late dormant to tight bloom with the 4 lb/gal or 80% WDG at 20 lb ai/A followed by treatments from tight bloom to petal fall at 10 lb ai/A. Whole mature fruit should be harvested and analyzed for captafol per se and THPI separately. Other metabolites may need to be determined if the required plant metbolism data indicate such a necessity.

13/ Data reflecting residues of captafol and THPI in or on sweet corn (kernels plus cob with husks removed) grown from seed treated with the 4 lb/gal F1C formulation at 4 oz ai/100 b of seed and treated with 15 aerially-applied foliar applications (made 4 days apart) of the 4 lb/gal F1C or 80% WDG formulation at 1 lb ai/A. Samples must be harvestd 5 days after the last foliar applications. Tests must be conducted in Fl.

Since seed treatement is no longer considered a non-food use for captafol, label restrictions prohibiting feeding or grazing of treated crops and limiting use to corn grown for fresh market should be added to both 24(c) labels (ID80005000 and FL8006400); alternatively, data reflecting residues in or on sweet corn forage and cannery waste following seed treatments, and appropriate tolerance proposals must be submitted.

14/ Residues of captafol and its THPI metabolite in or on cranberries 50 days after the last of three foliar applications made at 10-day intervals with the 4 lb/gal EC or the 80% WDG formulation at 5 lb ai/A, Tests should be conduceted in MS and WI.

15/ Residue data involving captafol residues (captafol per se and its THPI metabolite) in or on cucumbers as a result of a foliar spray when first true leaves appear and at weekly intervals thereafter using either the 80% WP, 80% WDG, or 4 lb/gal F1C formulation at 1.6 ai/A from tests conducted in CA and/or TX.

Residue data involving captafol residues (captafol per se and its THPI metabolite) in or on cucumbers following a single spray application of the 4 lb/gal F1C or 80% WDG at 3.25 lb ai/A directed to the bed soil after the last cultivation or when vines begin to run from tests conducted in southeastern states.

16/ Residue data for captafol and THPI (analyzed and reported separately) in or on macadamia nutmeats after 16 foliar treatments made twice weekly during the 8-week period in February and March. The studies should be done in Hawaii.

17/ Residue data involving residues of captafol (captafol per se and its THPI metabolite) in or on any melon variety other than watermelon as the result of a spray application of the 80% WP, 4 lb/gal F1C, or 80% WDG formulation at 2.5 lb ai/A (using 100-150 gal spray/A) beginning when first true leaves appear and repeated at weekly intervals thereafter from tests conducted in CA and TX.

Residue data involving residues of captafol (captafol per se and its THPI metabolite) in or on watermelons from aerial applications of the 80% WDG at 2.5 lb ai/A (using 5 gal spray/A) beginning when plants start to vine and repeated at 5- to 10-day intervals from tests conducted in any southeastern (FL, GA, or SC) and western (CA and TX) location.

Residue Data involving residues of captafol (captafol per se and its THPI metabolite) in or on watermelons from aerial applications of the 4 lb/gal FlC at 2.5 lb ai/A (using 5 gal spray/A) beginning when plants start to vine and at 5- to 10-day intervals thereafter from tests conducted in TX. Alternatively, this state label could be cancelled.

Residue data involving levels of other captafol metabolites may also be required if the requested plant metabolism data show other residues of concern to be present in significant amounts in mature plants.

18/ Same as with Apricots.

19/ Data reflecting residues of captafol and THPI in or on peanut nutmeats and hulls 14 days after the last of 12 foliar applications (made 10 days apart) of the 80% WDG formulation at 1.6 lb ai/A. Both aerial and ground applications must be represented. Plants must be grown from seed treated with one of the registered D formulations at 0.2 lb ai/100 lb of seed. Tests must be conducted in peanut production regions in FL (4%), GA (42%) TX (10%), and VA (8%); percentage of 1981 peanut crop production is given in parentheses (preliminary figures; Agricultural Statistics, 1982, p. 126). If GA can represent both AL (15%) and NC (14%), then 93% of the peanut production area will be represented.

Data reflecting residues of captafol and THPI in meal, crude oil, refined oil, and soapstock processed from nutmeats having measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

20/ Residues of captafol and its tetrahydrophthalimide (THPI) metabolite in or on onions (dry bulb) on the day of the last of 12 weekly applications of the 4 lb/gal FlC or the 80% WDG formulation at 1.25 lb ai/A. Tests should be conducted in CO (10%), ID (8%), or OR (14%), MI (8%), and NY (13%); percent contribution to annual U.S. dry bulb onion production is given in parenthesis.

Residues of captafol and THPI in or on green onions on the day of the last of 8-10 foliar applications of the 4 lb/gal FLC or 80% WDG applied weekly at 1.25 lb ai/A. Tests should be conducted in CA (40%) and TX (50%); percent contribution to annual U.S. green onion production is given parenthetically. Alternatively the labels and commidity definition could be changed from "onions" to "onions (dry bulb)."

Note that other metabolites of captafol may need to be sought in the above requested studies if the plant metabolism studies reveal additional residues of concern.

21/ Same as with Apricots.

22/ Residues of captafol and its THPI metabolite in or on whole pineapple fruits and forage grown from slips treated with a single dip application at 0.125 lb ai/gal (31.25 lb ai/A) followed by eight foliar spray treatments at 8 lb ai/A with either the 80% WP, 80% WDG, or the 4 lb/gal FlC formulation. Tests should be conducted in HI.

Determination of residues (captafol and its THPI metabolit) in juice and bran processed form captafol-treated pineapple bearing detectable, weathered residues of captafol.

23/ Residue data for captafol and THPI (analyzed and reported separately) from dried prunes processed from plums (fresh prunes) bearing measurable weathered residues. Exaggerated rates may be required to obtain such residue levels.

A tolerance for dried plums should be proposed based on this data, if necessary.

24/ Combined residues of captafol and THPI in or on whole potatoes harvested on the day of the last of 16 weekly applications of either a FlC, WDG or WP formulation at 1.6 lb ai/A. Tests must be conducted in CA, ID, ME, and WI.

Residues of captafol per se and its THPI metabolite in dried potatoes, potato chips, and granules processed from potatoes containing tolerance-level or above (>0.5 ppm) weathered residues of captafol.

25/ Data reflecting residues of captafol and THPI in or on taro root (corn) and foliage 11 weeks after the last of 23 foliar sprays (applied 7 days apart) with the 80% WDG formulation at 1.6 lb ai/A. Tests should be conducted in HI.

26/ Residue of captafol per se and its THPI metabolite in or on mature tomatoes harvested on the day of the last of 10 foliar applications (using ground and aerial equipment) with either the 4 lb/gal FlC, the 80% WP or the 80% WDG formulation at 2.5 lb ai/A; treatments are to begin when fruit is well formed and continued at 7-day intervals. Tests should be conducted in CA and FL using both aerial and ground equipment.

Residues of captafol per se and its THPI metabolite in or on mature tomatoes which received a single foliar application (at fruit formation) with the 4 lb/gal FlC or the 80% WDG formulation at 16 lb ai/A and (in a separate test with either the FlC or the WDG) two foliar applications, separated by 20 days, at 8 lb/A. Tests should be conducted in CA and FL using either ground or aerial equipment for application.

Residue data from greenhouse tests in which a single soil drench treatment with the 4 bl/gal FlC formulation is made at 24 lb ai/A 14 days prior to planting. Residues of captafol per se and THPI must be determined.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition[1]/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/
158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,C,E	No	--------	Yes (6 months)
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,C	No	--------	Yes (6 months)
161-3 - On soil	TGAI or PAIRA	A,	No	--------	Yes (6 months)
161-4 - In Air	TGAI or PAIRA	A	No	--------	Yes (6 months)
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,E	Partially[4]/	00096916	Yes (24 months)
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Partially[5]/		No
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	Partially[6]/	00026453	Yes (24 months)
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No	--------	Yes (24 months)
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,E	Partially[7]/	00096917 00096972	Yes[7] (6 monts)
163-2 - Volatility (Lab)	TEP	A,E	No	--------	Yes (6 months)
163-3 - Volatility (Field)	TEP	A,E	No	--------	Yes (6 months)

TABLE A

GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A	No	--------	Yes (24 months)
164-2 - Aquatic (Sediment)	TEP	C	No	--------	Yes (24 months)
Water	TEP	C	No	--------	
164-3 - Forestry	TEP	-	-	--------	No
164-4 - Combination and Tank Mixes					
164-5 - Soil, Long-term	TEP	A	No	---------	Yes 8/ (36 months)
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	partially 9/	00096919	Yes (24 months)
165-2 - Rotational Crops (Field)	TEP	A	No	----------	Yes (24 months)
165-3 - Irrigated Crops	TEP	C	No	----------	Yes (24 months)
165-4 - In Fish	TGAI or PAIRA	A,C	No	----------	Yes (24 months)
165-5 - In Aquatic Non-Target Organisms	TEP	-	-	----------	--
Reentry Studies					Yes 10/ (24 months)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA - Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than indicated below in this table.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

4/ Study 00096919 partially fulfills data requirements by providing information on the rate of carbonyl-labeled [^{14}C] captafol degradation a loamy sand soil and on the identification, formation and decline of [^{14}C] captafol degradate in aerobic soil. The study did not provide information on the 4 cyclohexene ring opening (degradation) in aerobic soil. An additional aerboic soil metabolism study is required utilizing 4 cyclohexene ring labeled captafol as the test substance. The study must be conducted as the same soil type and at the same concentration, temperature and moisture as the study in which carbonyl-labeled captafol was used as the test substance.

5/ Data from an anaerobic soil metabolism study need not be submitted if data from the anaerobic aquatic metabolism study study described in §162.3 of this subdivision have been submitted. An anaerobic aquatic metabolism study has been submitted which partially fulfills data requirements.

6/ One study has reviewed, 00026453, and it is scientifically valid. This study partially fulfills data requirements by providing information on the rate of anaerobic aquatic degradation of carbonyl-labeled [^{14}C] captafol in a loamy sand soil, and on the identification, formation and decline of [^{14}C]1 captafol degradates in water plus loamy sand. The study did not provide information on the 4-cyclohexene ring opening (degradation) in anaerobic water plus loamy sand. An additional anaerobic aquatic metabolism study is required utilizing 4-cyclohexene ring-labeled captafol as the test substance. The study must be conducted using water plus sediment obtained from and representative of that found at the intended aquatic use site. This study must be submitted in order to waive the anaerobic soil data requirements.

7/ Two studies partially fulfill data requirements by providing data on the mobility of captafol residues aged in sandy loam soil 20-30 days, however the aged captafol residue were not characterized (00096917), and on the mobility of [^{14}C]captafol in silty clay loam, sandy loam, clay, and clay loam soils (00096972). Additional data are needed on the mobility of aged captafol residues (captafol) and its degradates in soil. For the study of pesticide degradates mobility, captafol must be aged for 30 days or one half-life using appropriate laboratory conditions, soil sampling protocols, and analyses. The degradates must be identified. This will fulfill data requirements for terrestrial, food crop use patterns. To fulfill the data requirements for greenhouse food crop use patterns, batch equilibrium (adsorption/desorption) studies are required on a minimum of four soils. The soils selected must be soils such as sand (agricultural), sandy loam, silt loam, clay or clay-loam, each having a pH within a range of 4-8. Batch equilibrium (adsorption/desorption) studies on one aquatic sediment obtained from or representative of the of the proposed aquatic use area required to fulfill the aquatic food, crop use patterns.

Based on leaching and aerobic soil metabolism studies data requirements, captafol is immobile in soil varying in texture from clay to sandy loam. The immobility of captafol in soil and its degradation in soil are expected to result in a low potential for ground water contamination by captafol. However, aged [^{14}c] captafol residues are mobile in sandy loam, but as was true for the parent compound, the degradation of captafol degradates is expected to reduce the potential for groundwater contamination by captafol degradates.

The Agency is concerned about the contamination of ground water by captafol and its metabolites. Data required for the evaluation of the potential for contamination of ground water are being required on an accelerated basis.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

8/ The data requirements for Long Term Soil Dissipation Studies will be based on the results of Aerobic Soil Metabolism and Terrestrial Field Dissipation Studies.

9/ Study 0009691 partially fulfills data requirements by providing data on the uptake of aged $[^{14}C]$captafol residues by rotated carrots (roots and tops) grown under confined conditions. Additional studies are needed providing information on the identity of $[^{14}C]$ captafol residues ages in a sandy loam soi by 2 rotated small grain and rotated leafy vegetable. The results of this study (00096919) indicate that field accumulation studies on rotational crops are required to establish rotation restriction intervals or to determine if tolerance are needed for rotational crops.

10/ The Agency is imposing a 24-hour reentry interval pending receipt and evaluation of reentry data.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Data Requirement	Composition[1/]	Use [2/] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[2][3/]
§158.145 Wildlife and Aquatic Organisms					
Avian and Mammal Testing					
71-1 Acute Avian Oral Toxicity	TGAI	A,C	Yes	00096964*	No
71-2 Acute Avian Dietary Toxicity	TGAI	A,C			
a. Waterfowl			Yes	GS0122039*	No
b. Upland game			Yes	00096965*	
71-3 Wild Mammal Toxicity	____		____	____	No
71-4 Avian Reproduction	TGAI	A,C	Yes	00030479* 00041447*	No
71-5 Simulated and Actual Field Testing on Mammals and birds	TEP	A	No		Reserved[4]
Aquatic Organisms Testing					
72-1 Acute Freshwater Fish Toxicity a. Warmwater	TGAI	A,C	Yes	GS0122036* GS0122037* GS0122038*	No
	TEP	A,C	Yes	00003503*	No
c. Coldwater	TGAI	A,C	Yes	GS0122034* GS0122033* GS0122035* 00069607*	No

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

	Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
72-2	Acute Toxicity, Freshwater Invertebrates	TGAI	A,C	Yes	00062907* 00003503* 00097842**	No
		TEP	A,C	Yes		
72-3	Acute Toxicity, Estuarine and Marine Organisms	TGAI	A,C	No		Yes[5]
	Oyster	TEP	A,C	No		Reserved[6]
	Shrimp					
	Marine fish					
72-4	Fish Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI,PAI	A,C	No		Reserved[7]
72-6	Aquatic Organisms Accumulation	TGAI,PAI	A,C	No		Reserved[7]
72-7	Simulated or Actual Field Testing-Aquatic Organisms	TEP	A,C	No		Reserved[7]

1/ Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient; TEP = typical end-use product.

2/ The use patterns are coded as follows: A = terrestrial non-food crop; C = Aquatic food crop; D = aquatic non-food crop; E = greenhouse food crop; F = greenhouse non food crop; G = Forestry; H = domestic outdoor; I = indoor.

3/ Data must be submitted no later than 6 months after the publication of this standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR CAPTAFOL

Footnotes (continued)

4/ Pending results of environmental fate data.
5/ Uses such as citrus (with acreage in excess of 300,000 acres in coastal counties).
6/ Data may be required to support such uses as citrus pending the results of environmental fate data.
7/ Data may be required pending the result of environmental fate data.
* Study fulfills requirements on its own.
** Study in conjunction with another study fulfills requirements.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This Section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

---

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CAPTAFOL

Data Requirement	Composition[b]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
EPA REG. NO. 239-2230 (97%T)[a]				
§158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Product Identity and Diclosure of Ingredients	TGAI	Yes	GS0122030	No
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	Partially	GS0122032	Yes
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	Partially	GS0122028, GS0122030	Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	GS0122029	No
63-3 - Physical State	TGAI	Yes	GS0122029	No
63-4 - Odor	TGAI	Yes	GS0122029	No
63-5 - Melting Point	TGAI	Yes	GS0122029	No
63-6 - Boiling Point	N/A[d]	N/A		No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		No

---

[a] The 97% technical (T) also serves as a manufacturing-use product.

[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.

[c] Data must be submitted no later than 6 months from the date of this Standard.

[d] Not required because the 97% technical is a solid at room temperature.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CAPTAFOL

Data Requirement	Composition[b]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[c]
EPA REG. NO. 239-2230 (97%T)[a]				
§158.120 Product Chemistry (continued)				
63-8 - Solubility	TGAI or PAI	Partially	GS0122051	Yes
63-9 - Vapor Pressure	PAI	No		Yes
63-10 - Dissociation Constant	PAI	No		Yes
63-11 - Octanol/ Water Partition Coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	Yes	GS0122050	No
other Requirement:				
64-1 - Submittal of Samples	N/A	N/A		No

---

[a] The 97% technical (T) also serves as a manufacturing-use product.

[b] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.

[c] Data must be submitted no later than 6 months from the date of this Standard.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CAPTAFOL

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	GS 0122046	No
81-2 - Acute Dermal Toxicity	MP	Yes	GS 0122046	No
81-3 - Acute Inhalation Toxicity -Rat	MP	No	-	Yes (6 months)
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	GS 0122049	No
81-5 - Primary Dermal Irritation	MP	Yes	00087538	No
81-6 - Dermal Sensitization	MP	Yes	00014690	No

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CAPTAFOL

§158.135 Toxicology
(continued)

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than 6 months from the date of receipt of this Standard.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies to end-use products only to the extent described under Section II of this document. Otherwise, the following information pertains exclusively to manufacturing-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix IV-1 and IV-2], as indicated by the following paragraphs of this chapter of the guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this Section and/or Section II, EPA may issue a notice of intent to cancel the registration under FIFRA §6(b)(1).

A. Label Contents

40 CFR §162.10 (Appendix IV-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table entitled: "Labeling Requirements of FIFRA, As Amended".

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix IV-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix IV-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix IV-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix IV-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Henry M. Jacoby, Product Manager 21
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-1900

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

   d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, the registrant may submit such labeling. (End-use product labeling needs to comply specifically with the instruction in Section II of this guidance document.) The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for stortage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

After the Supreme Court has ruled on the Monsanto Decision, you will be informed as to when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the associated data support information.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

MRID No.	
00025129	Cheng, H.M. 1976. Metabolism of carbonyl-^{14}C-difolatan in young tomato and corn plants. Chevron Chemical Co. File No. 721.14. Dated December 2 and submitted by Chevron Chemical Co. under PP#7F1962(099190).
00025130	Cheng, H.M. 1976. Absorption, translocation, and metabolism of [carbonyl-^{14}C]THPI in young tomato plants. Chevron Chemical Co. File No. 721.14. Dated August 16 and submitted by Chevron Chemical Co. under PP#7F1962(099190).
00096919	Pack, D.E. 1973. ^{14}C-difolatan uptake from soil by carrots - EPA protocol. Chevron Chemical Co. File No. 773.21/Difolatan. Dated October 12. Submitted by Chevron Chemical Co. as Reference No. 4 in "Difolatan fungicide - Supplementary Environmental Data" (120308).
00096916	Pack, D.E. 1973. The soil metabolism of carbonyl-^{14}C-difolatan. Chevron Chemical Co. File No. 773.21. Dated November 287. Submitted By Chevron Chemical Co., as Reference No. 1 in "Difolatan fungicide - Supplementary Environmental Data" (120308).
00072884	Pack, D.E. 1980. Analysis of soybeans grown from seeds treated with ^{14}C-captafol - greenhouse study. Chevron Chemical Co. File No. 721.14. Dated July 21. Submitted by Chevron Chemical Co. to RCB.
0081808	Potter, J.L. 1965. Preliminary studies on the in vitro degradation of difolatan by crop macerates and filtrates. Dated May 5, prepared by the California Chemical Co., and submitted by Chevron Chemical Co. under PP#5G0453(114475) and PP#6F0492(1114612).
05003661	Solel, Z. and L.V. Edgington,. 1973. Transcuticular movement of fungicides. Phytopathology, Vol. 63, April, pp. 505-510. (Not registrant submitted.)
00096829	California Chemical Co. 1965. Technical Report Nos. 5K7926 and 5K7945. Submitted under PP#5G0453(114475).
00096830	California Chemical Co. 1965. Technical Report Nos. 5K7926 and 5K7945. Submitted under PP#5G0453(114475).

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

MRID No.	
00025952	Cheng, H.M. of Chevron Chemical Co. 1977. Metabolism of difolatan in chickens. Report dated November 3, 1975. Submitted under PP#7F1962(096160).
00025119	Cheng, H.M. of Chevron Chemical Co. 1977. Metabolism of ^{14}C-carbonyl captofol in rats-characterization and quantification of ^{14}C in tissues. Report dated February 26, 1979. Submitted under PP#7F1962(099190).
00025120	Cheng, H. M. of Chevron Chemical Co. Metabolism of [carbonyl-^{14}C] THPI and [carbonyl-^{14}C]THPI-epoxide by rats. Report dated June 15, 1979. Submitted under PP#7F1962(099190).
00025124	Cheng, H. M. of Chevron Chemical Co. Metabolism of carbonyl ^{14}C captafol in a lactating goat. Report dated July 9, 1979. Submitted under PP#7F1962(099190).
00025127	Crossley, J. of Chevron Chemical Co. The stability of difolatan in human blood. Report dated October 4, 1967. Submitted under PP#7F19692(099190).
00061996	Crossley, J. of Chevron Chemical Co. Difolatan: fate in animals. Report dated October 29, 1968. Submitted under PP#9F0797(115899).
00053240	Crossley, J. of Chevron Chemical Co. The fate of difolatan in a lactating ruminant (goat). Report dated June 10, 1970. Submitted under PP#9F0797(115899).
00096902	Lee, H. of Chevron Chemical Co. Metabolism of difolatan in rats: identification of urinary metabolites. Report dated February 28, 1972. Submitted under PP#7F1962(096160).
00096847	California Chemical Co. 1964. Difolatan residue analysis-thin layer chromatographic method (Method RM-6). Submitted under PP#5G0453(114470).
00096848	California Chemical Co. 1964. Difolatan metabolism - the analysis of residues of dichloroacetic acid using microcoulometric gas chromatogrpahy (method RM-6C) Submitted under PP#5G0453(114470).

Appendix II-1

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

MRID No.	
00096843	California Chemical Co. 1965. The analysis of residues of difolatan and three tetrahydrophthalic acid derivatives (Method RM-6-D). Submitted under PP#5G0453(114473).
00091215	Chevron Chemical Co. 1965. Difolatan residue analysis by electron capture gas chromatography (Method RM-6B). Submitted under PP#6F0492(114607).
	Chevron Chemical Co. 1965. Difolatan residue methods - a comparison of RM-6 and RM-6B for several crops. By P. Berteau. Submitted under PP#6F0492(114607).
00091214	Chevron Chemical Co. 1966. Difolatan residue analysis - thin layer chromatographic method (Method RM-6, revised). Submitted under PP#6F0492(114607).
00052318	Chevron Chemical Co. 1973. Addendum to RM-6B for determination of residues of difolatan in sweet corn, tomatoes, and peanuts. Submitted under PP#3F1412(118300).
0031709	Chevron Chemical Co. 1975. Determination of captafol residues by gas chromatography method RM-6E-1. Submitted under PP#6E1775.
00025123	Chevron Chemical Co. 1976. Determination of residues of captan and its metabolites in animal tissues (Method RM-1G-1). Submitted under PP#7F1962(096160).
00096911	Chevron Chemical Co. 1978. Determination of captafol residues by gas chromatography method RM-6E-2. Submitted under PP#7F1962(099190).
00025123	Chevron Chemical Co. 1979. Determination of captafol, captan, THPI, and 3-OH THPI in tissues and eggs and determination of captan THPI, 3-OH THPI, and 5-OH THPI in milk and cream. Submitted under PP#7F1962(099190).
00025133	Chevron Chemical Co. 1979. Determination of residues of THPI in crops - Residue Method RM 6J-1 and RM 1J-1. By E.J. Elliott, J.C. Lai and F.J. Schwab. Submitted under PP#8F2047(070837).
00091274	Chevron Chemical Co. 1966. Storage stability of difolatan residue samples. File: 741.10/Difolatan. Test Nos. 712-716, 776, 831, and 871. Submitted under PP#6F0492(114611).
00096889	IR-4. Rutgers University. 1976. Test Nos. 3210, 3209, 3241, 3011, and 3202-3205 in Section D of PP#6E1175 (undesignated accession number).

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

MRID No.	
00096828	Chevron Chemical Co. 1966. Residue data sheets for experiment T-714. Section D. PP#6F0492(114607).
00096817	Chevron chemical Co. 1967. Test Nos. 710, 716, 717, 869, and 870. Residue data sheets in Section D of PP#6F0492(114607).
00096858	Chevron Chemical Company. 1966. Section A of PP#6F0492(114510).
00097842	Sanders, H.O. (1969) Toxicity of Pesticide to the Crustacean Gammarus iacustris. By U.S. Fish and Wildlife Service, Fish-Pesticide Research Laboratory. Washington, D.C.: USFWS, (Technical papers of the Bureau of Sport Fisheries and Wildlife 25; Stauffer T-2214; published study; CDL:246020-K)
00069607	Thompson, C.M.; Griffen, J.; Boudreau, P.; et al. (1980) Acute Toxicity of Difolatan Technical (Sx-945) to Bluegill Sunfish ("Lepomis macrochirus"): ABC Report #26575/#26576. (Unpublished study received Feb 2, 1981 under 239-2369; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif., CDL:244371-8)
00062907	Forbis, A.D.; Boudreau, P.; Cranor, W.; et al. (1980) Static Acute Toxicity of Difolatan Technical (SX-945) to "Daphnia magna" (S-1798): ABC Report # 25857. (Unpublished study received Nov 19, 1980 under 239-2211; prepared by Analytical Bio Chemistry Laboratories, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:243833-A)
00030479	Beavers, J.B.; Fink, R. (1979) Final Report: One-Generation Reproduction Study--Mallard Duck: Project No. 162-109. (Unpublished study including addendum and letters dated Dec. 1, 1978; Mar 1, 1979; Apr 2, 1979 and Nov 14, 1978 from J.B. Beavers to Francis X, Kamienski, received Feb 21, 1980 under 239-2211; prepared by Wildlife International, Ltd., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:099267-A)
00096964	Fink, R.; Beavers, J.B.; Grimes, J.: et al. (178) Final Report: Acute Oral LD_{50}--Bobwhite Quail: Difolatan Technical: Project No. 162-101. (Unpublsihed study received Dec 13, 1978 under 239-2211; prepared by Wildlife Internatioanl Ltd, and Washington College, submitted by Chevron Chemical Col, Richmond, Calif.; CDL:236618-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

MRID No.

00096965 Fink, R.; Beavers, J.B.; Grimes, J.; et al. (1979) Final Report: Eight-day Dietary LC_{50}--Bobwhite Quail: Difolatan Technical (SX-945): Project No. 162-114. (Unpublished study received Mar 13, 1979 under 239-2211; prepared by Wildlife International Ltd. and Washington College, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:237803-B)

00041447 Beavers, J.B.; Fink, R.; Grimes, J.; et al. (1979) Final Report; One-Generation Reproduction Study--Bobwhite Quail: Project No. 162-108. (Unpublished study including addendum and letters dated Dec. 11, 1978; Mar 1, 1979; Apr 2, 1979; Apr 25, 1979 and Nov 14, 1978 from J.B. Beavers to Francis X, Kamienski, received Feb 21, 1980 under 239-2211; submitted by Chevron Chemical Co., Richmond, Calif., CDL:099267-B)

00003503 Johnson, W. and M. Finley 1980. Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. USDI Publication 137, Washington, D.C.

00014690 Cavalli, R.D. (1970) Skin Sensitization Potential of RE 12,420 (75% SS):SOCO 156/III:85. (Unpublished study received Jun 21, 1972 under 239-EX-61; submitted by Chevron Chemical Co., Richmond, Calif. CDL:223505-U).

00046435 Shirasu, Y., M. Moriya, K. Kato, A. Furuhashi, and T. Kada; (1976) Mutagenicity Screening of Pesticides in the Microbial System. Mut. Research 40, 19-30.

00061996 Crossley, J. (1968) Difolatan: Fate in Animals: File No. 721.14. (Unpublished study received Apr 15, 1969 under 9F0797; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:091370-E)

00087538 Cerkanowicz, D.A. (1981) The Skin Irritation Potential of Difolatan 80 WDG: Socal 1837 (S-1977). (Unpublished study received Dec 1, 1981 under 239-2495; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:246325-E)

00027544 Bradfield, L. G. (1980) Dominant Lethal Study of Difolatan Technical: Socal 1354. (Unpublished study received Feb. 11, 1980 under EPA Registration File 239-2211; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:099266-A).

Appendix II-1

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

MRID No.	
00088817	Chevron Chemical Company (1981) Difolatan Technical (SX-947) Lifetime Mouse Oncogenicity Feeding Study: Socal 1330 (S-1391). (Unpublished study received Jul 30, 1981 under 239-2211; CDL: 246380-A)
00093672	Reno, F.E., J.L. Barlow, G.A. Burdock, et. al. (1981) Subchronic Toxicity Study in Rats: Difolatan Project No 2107-102. Final Rept. (Unpublished study received Dec 15, 1981 under 239-2230; prepared by Hazleton Laboratories America, Inc., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:246577-A)
00096902	Lee, H. (1972) Metabolism of Difolatan in Rats: Identification of Urinary Metabolites: File No. 721.14. (Unpublished study received Jun 9, 1977 under 239-2211; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:096157-D)
05001994	Robens, J.F. (1970) Teratogenic Activity of Several Phthalimide Derivitives in the Golden Hamster. Toxicology and Applied Pharm. 16, 24-34.

Appendix II-1

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

GS No.

GS0122001 Buttler, B. and W. D. Hormann. 1981. High-pressure liquid chromatographic determination of captan, captafol, and folpet residues in plant material. J. Agric. Food Chem. Vol. 29(2):257-260.

GS0122002 Chevron Chemical Co. 1973. Revision of difolatan residue analysis by electron capture gas chromatography method RM-6B. Submitted under PP#4E1480(093931).

GS0122003 Chevron Chemical Co. 1980. Determination of captafol and THPI residues in crops (Method RM-6K-1). Submitted under PP#8F2047 (070837).

GS0122004 Chevron Chemical Co. 1980. Determination of captafol and THPI residues in crops (Method RM-6K-2). Submitted under PP#8F2047(070837).

GS0122005 Chevron Chemical Co. 1981. Determination of captafol and THPI residues in coffee beans. (Method RM-6L). Submitted under PP#8F2047(070837).

GS0122006 Ngoran, N., C.D. Ercegovich, K.D. Hickey and R.O. Mumma. 1979. An improved analytical procedure for captafol residues in apple wood, leaves, and fruit. J. Agric. Food Chem. Vol. 27 (6):1167-1170.

GS0122007 Chevron Chemical Co. 1970. Test Nos. 1171, 1250, 1251, 1356, 1357 (Sample Nos. 1, 2, 4, and 5), 1430, 1501, 1543, 1715, and 1802 in Section D of PP#0F0895(116328).

GS0122008 Chevron Chemical Co. 1966. Residue data sheets for experiments T-708, T-718, T-785, T-862. Section D. PP#6F0492(114607).

GS0122009 Chevron Chemical Co. 1966. Residue data sheets for experiments T-1176, 1175. Section D. PP#6F0492(114605).

GS0122010 Chevron Chemical Co. 1966. Residue data sheets for experiments T-1181, T-1182. Section D. PP#6F0492(14611).

GS0122011 Chevron Chemical Co. 1968. Residue data sheets for experiments "T"-2647-2650, 3229-3231, 3245-3248, 2660-2663, 3249, 3250, 3252, 3253, 3424, 3580-3582, 3825, 3826, 4031, 4032, 4991, 5027, 5028. Section D. PP#8E2062 (096918 and 099965).

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

GS No.

GS0122012 Chevron Chemical Co. 1971. Residue data sheets for tests T-1608, T-1641, T-1642, T-1643, T-1644, T-1769, T-1770, T-1771, T-1773, T-1774. Submitted in Section D. PP#1F1020(116849).

GS0122013 Chevron Chemical Co. 1973. Test nos. 977, and 2420-2424 in Section D of PP#3F1412(118300).

GS0122014 Chevron Chemical Co. 1971. Test nos. 963, 964, 965, 1808, and 1809 in Section D of PP#1F1020(116849).

GS0122015 Chevron Chemical Co. 1970. Residue data sheets for experiments T-1636, T-1637, T-1638, T-1872, T-1752, T-1870, T-1871. Section D. PP#0F0895(116328).

GS0122016 Chevron Chemical Co. 1981. Test No. T-5401 in a captafol amendment entitled Difolatan 80 Water Dispersible Granules EPA Reg. No. 239-NEW, 12-03. Residue Chemistry Data submitted by Chevron Chemical Co. on November 18, 1981 to RCB (under 239-2495; in Accession No. 246324).

GS0122017 Chevron Chemical Co. 1976. Test nos. 2636, 2637, 2638, 2793, 2860, 2861, 3038, 3185, 3186, 3187, 3359, and 3360 in Section D of PP#6F1676 (no accession number available).

GS0122018 Chevron Chemical Co. 1974. Test Nos. 2628, 2629, 2630, and 2631 in Section D of PP#4G1420(118327).

GS0122019 Chevron Chemical Co. 1971. Test Nos. 966-968 and 1003 in Section D. Submitted under PP#1F1020 (116849).

GS0122020 Chevron Chemical Co. 1970. Test Nos. 1518, 982, 1448, and 1429 in Section D of PP#0F0895(116328).

GS0122021 Chevron Chemical Co. 1966. Residue data sheets for experiment T-1183, T-1184, T-1190. Section D. PP#6F0492(114611).

GS0122022 Chevron Chemical Co. 1970. Test Nos. 778-780, 826, 1138-1141, 1342-1349, and 1716-1718 in Section D of PP#0F0895(116328).

GS0122023 Chevron Chemical Co. 1983. 12.03. Residue chemistry data to support an amendment to the difoloatan 4 flowable (EPA Reg. No. 239-2211-AA) label for potatoes to add sprinkler irrigation applications. Submitted February 16, 1983 (249527).

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

GS No.

GS0122024 IR-4. Rutgers University. 1974. Section D of PP#4E1480(093931).

GS0122025 Chevron Chemical Co. 1966. Test Nos. 711, 890, and 891 in Section D of PP#6F0492(1146505).

GS0122026 Chevron Chemical Co. 1966. Test Nos. 1177 and 1178. Submitted under PP#6F0492(114605).

GS0122027 Chevron Chemical Co. 1981. Test Nos. 5400 and 5404. 12-03. Residue chemistry data to support a new label registration for difolatan 80 water dispersible granules. EPA Reg. No. 239-NEW. Submitted November 18, 1981 (246324).

GS0122028 Chevron Chemical Company, Ortho Division. 1965. Ortho method of analysis D-VIII, Difolatan by Gas Chromotography data 2/8/65, PP#6F0492(114612).

GS0122029 Chevron Chemical Company. 1966. Data sheets for EPA Reg. No. 239-2230 in PP#6F0492(114612).

GS0122030 Chevron Chemical Company, Ortho Divison. 1967. Data from correspondence sent to EPA on EPA Reg. No. 239-2230 data 5/25/67, and located in the registration jacket.

GS0122031 EPA. 1975. Captafol. EPA-1 (tentative), In Manual of Chemical Methods for Pesticides and Devices. EPA, OTS.

GS0122032 Sittig, Marshall (ed.). 1977. Pesticides Process Encyclopedia. Corp. Park Ridge, NJ. p.82.

GS0122033 U.S. EPA. 1980. Report on Toxicity of Difolatan Technical to Rainbow Trout. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, MD. Flow Through, Test No. 2466, unpublished report.)

GS0122034 U.S. EPA. 1976. Report on Toxicity of Captafol Technical 97% to Rainbow Trout. (U.S. EPA Chemical and Biological Investigations Branch, Beltsville, MD. Static Jar, Test No. 7/14/76, unpublished report.)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

GS No.

GS0122035 U.S. EPA. 1980. Report on the Toxicity of Difolatan Technical to *Daphnia magna*. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville MD, Static Jar, Test No. 2458, 10/24/80, unpublished report.)

GS0122036 U.S. EPA 1980. Report on Toxicity of Difolatan Technical to Bluegill Sunfish in a Static Test. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, MD. Static Jar, Test No. 2465, 11/19/80, unpublished report.)

GS0122037 U.S. EPA. 1976. Report on Toxicity of Captafol Technical 97% on Bluegill Sunfish. (U.S. EPA, Chemical and Bological Investigations Branch, Beltsville, MD. Static Jar. Test No. 994, 7/14/76, unpublished report.)

GS0122038 U.S. EPA. 1980. Report on the Toxicity of Technical Difolotan to Bluegill Sunfish in a Flow-through Test. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, MD. Flow Through, Test No. 2465, 11/19/80, unpublished report.)

GS0122039 Beavers, J.B., and R. Fink. 1979 Final Report: Eight-day Dietary LC_{50}-Mallard Duck: Difolatan Techincal (SX-945): Project No. 162. (Unpublished study received under 239-2211; prepared by Wildlife International ltd. and Washington College, Submitted by Chevron Chemical Co., Richmond, Calif.; CDL:237803-B.)

GS0122040 Moriya, M., K. Kato, and Y. Shirasu. (1978) Effects of Cysteine and a Liver Metabolic Activation System on the Activities of Mutagenic Pesticides., Mut. Res. *57*, 259-263

GS0122041 Tezuka, H., N. Ando, R. Suzuki, M. Terahata, M. Moriya, and Y. Shirasu. (1980) Sister-Chromatid Exchanges and Chromosomal Aberrations in Cultured Chinese Hamster Cells Treated with Pesticides Positive in Microbial Reversion Assays. Mut. Res. *78*, 177-191.

GS0122042 Bio/Dynamics, Inc. (1983) Teratology Study in Rats of Difolatan Technical. Project #83-2716. Oct. 14, 1983. (Unpublished study received under 239-2230; submitted by Chevron Chemical Co, Richmond, Calif.; EPA Acc. No. 251812.)

Appendix II-1

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

GS No.	
GS0122043	Bio/Dynamics, Inc. (1983) Two-Generation Reproduction Study in Sprague-Dawley Rats. Project #80-2530. Oct. 10, 1983. (Unpublished study received under 239-2230; submitted by Chevron Chemical Co, Richmond, Calif.; EPA Acc. No. 251972-251977.)
GS0122044	Hazleton Laboratories. (1983) 2 Year Chronic Toxicity Study in Rats of Difolatan Technical (SX-945). #2107-103. June 15, 1983. (Unpublished study received under 239-2230; submitted by Chevron Chemical Co., Richmond, Calif.; EPA Acc. No. 250921-250924.)
GS0122045	Bioresearch Laboratories Ltd. (1983) Teratology Study in the Rabbit with Captafol Technical. #81154. Dec. 6, 1983. (Unpublished study received under 239-2230; submitted by Chevron Chemical Co., Richmond, Calif.; EPA Acc. No. 253055-253056.)
GS0122046	Chevron Chemical Co. (1984) Toxicology Data. March 1, 1984. S-2153, 2154, 1967, and 1858. (Unpublished studies received March 2, 1984 under 239-2230; submitted by Chevron Chemical Co., Richmond, Calif.; EPA Acc. No. 252599.
GS0122047	EG&G/Mason Research Institute. (1983) *In Vivo* Cytogenetics Study in Rats with Chevron Difolatan Technical (SX-945). Oct. 7, 1983. MRI-224-CCC-83-31 (Unpublished study received under 239-2230; submitted by Chevron Chemical Co., Richmond, Calif.; EPA Acc. No. 252331-252332.
GS0122048	Bio/Dynamics Inc. (1984) Teratology Study in Rabbits with Captafol Technical. Feb. 22, 1984. Proj. No. 83-2734. (Unpublished study received under 239-2230; submitted by Chevron Chemical Co., Richmond, Calif.; EPA Acc. No. 248965.

Appendix II-1

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

GS No	
GS0122049	Chevron Chemical Co. (1981) Primary Eye Irritation in Rabbits. Sept. 11, 1981. Socal 1838. (Unpublished study received under 239-EUOL; submitted by Chevron Chemical Co., Richmond, Calif.; EPA Acc. No. 246326.
GS0122050	Chevron Chemical Co. 1981. 12.03. Residue chemistry data to support a new label registration for difolatan 80 water dispersible granules. Submitted November 18, 1981 (246324).
GS0122051	California Chemical Company, Ortho Division, 1963. Report entitled "Difolatan- A Preliminary Report on It's Hydrolysis and Related Reactions" dated 7/30/63. File No. 740.10. By P. E. Berteau. Located in PP No. 6F0492 (114610).
GS0122052	Chevron Chemical Co. 1965. Difolatan residue methods - a comparison of RM-6 and RM-6B for several crops. By P. Berteau. Submitted under PP No. 6F0492 (114607).
GS0122053	Chevron Chemical Co. 1973. Revision of difolatan residue analysis by electron capture gas chromatography method RM-6B. Submitted under PP No. 4E1480 (093931).
GS0122054	Davis, J. 1978. An analysis of Exposure Data Obtained During the Airblast Spraying of Orchards with Selected Pesticides. Unpublished EPA Laboratory Report.
GS0122055	Reinert, J. C., and D. J. Severn. (?) Dermal Exposure to Pesticides: EPA's Viewpoint. ACS Symposium Series (in print).
GS0122056	Jensen, J. K. 1982. Applicator Exposure Analysis, Captan Position Document 2/3. Final Report, Environmental Fate Branch, Hazard Evaluation Division, US EPA.
GS0122057	Versar, Incorporated 1984. Applicator and Mixer/Loader Exposure to Pesticides During Ground Boom Spraying Operation, Final Report. EPA Contract No. 68-01-6271, Task No. 48.
GS-122058	US EPA 1980. Position Document 2/3 on Wood Preseratives.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Captafol Standard

GS No

GS0122059 Felthausen, R. W. 1977. Data Review of Interim Report for Experimental Use Permit for Aerial Application on Cranberries (239-EUP-62). Data review dated January 31, 1977: Environmental Safety, Efficacy and Ecological Effects Branch, US EPA.

GS0122060 Felthausen, R. W. 1977. Data Review of Interim Report for Experimental Use Permit for Aerial Application on Cranberries (239-EUP-62). Data review dated May 7, 1977: Environmental Safety, Effficacy and Ecological Effects, US EPA.

Appendix II-2

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

Appendix II-3

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.______________ Guidance Document for______________________

Date______________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

~~(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)~~

~~[44 FR 27953, May 11, 1979]~~

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government:

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000.	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above [illegible]0° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five~~

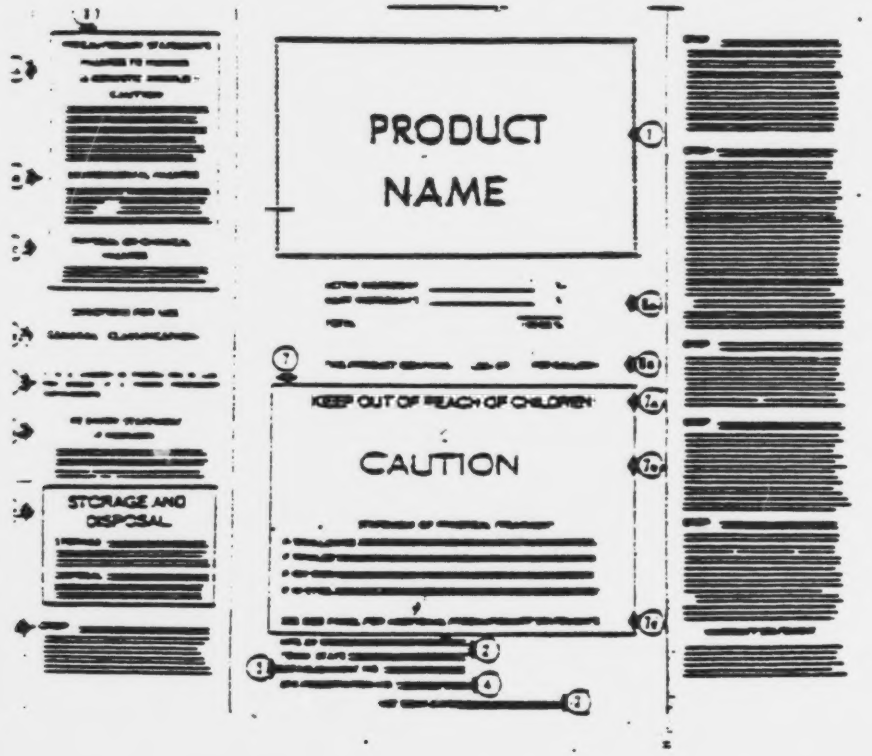
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

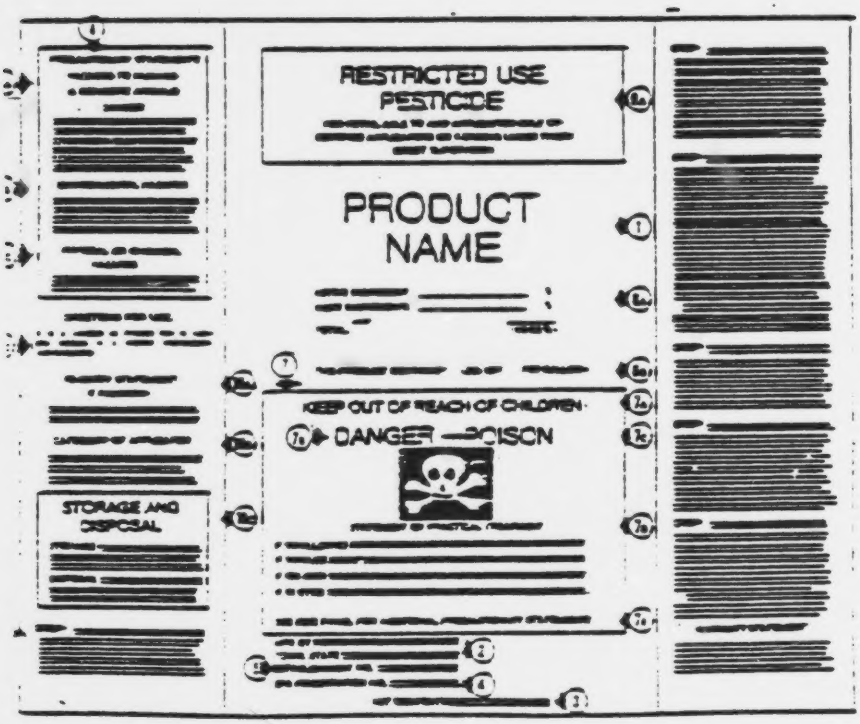
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

SAMPLE LABELS


PRODUCT
NAME
KEEP OUT OF REACH OF CHILDREN
CAUTION
STORAGE AND
DISPOSAL
1
2
3
4
7

General Use Pesticide


RESTRICTED USE
PESTICIDE
PRODUCT
NAME
KEEP OUT OF REACH OF CHILDREN
DANGER — POISON
STORAGE AND
DISPOSAL
1
2
3
4
7

Restricted Use Pesticide

Appendix IV-3

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

Appendix IV-4

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexaethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, O,O-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List) Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

CAPTAFOL*

TYPE PESTICIDE: Fungicide/Acaricide

FORMULATIONS: Tech (97%); D (35%, 60%, 65%); WP (25%, 70%, 80%); EC (39%); FlC (27%, 4 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: Dosage rates are expressed in active ingredient (exceptions are registration number 3008-27 which is used for surface mold control and 239-2313 listing uses for peach and nectarine).

Agricultural Crop Tolerances: All are listed at individual crop sites.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS			
Apple		0.25 ppm No preharvest interval through 12.0 pounds per acre. Do not prune following captafol application. Do not apply oil after captafol application as phytotoxicity may occur. Captafol applications later than 1/4 inch green tip stage may produce foliage injury and/or fruit russeting.	/04001AA
Apple scab (venturia)	0.8 lb/100 gal [use up to 600 gal/A] (80% WP)	Dormant or delayed dormant application. Apply a single spray at up to 1/4 inch green tip stage of growth.	FEAJVAG
	12.0-20.0 lb/A [Use 100 to 400 gal] (4.0 lb/gal FlC) (80% WP - granular size)	Use limited to Midwestern and Eastern States. Dormant or delayed dormant application. Make a single application during dormant period or up to 1/4 inch green tip stage. Use the higher rates and gallonage for larger trees. This application gives scab protection through the pink stage. For later scab protection, use another suitable fungicide.	

*(cis-N-((1,1,2,2,-tetrachloroethyl)thio)-4 cyclohexene-1,2,-dicarboximide)

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Apple (continued)			
	5.0 lb/100 gal [use up to 400 gal/A] (4.0 lb/gal FlC)	Use limited to Midwestern and Eastern States. Dormant or delayed dormant application. Make a single application during dormant period or at up to 1/4 inch green tip stage. Use the higher gallonage for larger trees. This application gives scab protection up to petal fall. For later scab protection, use another suitable fungicide.	
Apricot		30 ppm No preharvest interval through 12.8 pounds per acre.	/05001AA
	400 gal/A (80% WP) or 1.5 fl oz (3 tbls) 27% FlC/gal (27% FlC)	rates in fall before rains begin and repeat in late winter prior to bud swell or apply higher rates as single treatment after leaves have dropped or prior to fall rains.	
Scab (Cladosporium) Brown rot blossom blight	0.8-1.0 lb/ 100 gal (80% WP)	Delayed dormant and foliar application. Use sufficient spray per acre depending on size of tree to provide full coverage. Apply at prebloom, full bloom, petal fall and shuck split and repeat at 10 to 14 day intervals though harvest. Do not apply after shuck split in California, Oregon, or Washington, or if fruit is to be dried.	FEAJCCV FBADMCB
Blueberry		25 ppm 21 day preharvest interval through 4.0 pounds per acre.	/01009AA
Fusicoccum canker	2-4 lb/A [use 20-250 gal/A] (4.0 lb/gal FlC) (80% WP - granular size)	Delayed dormant and foliar application. Begin applications at bud break and repeat at 4 to 6 week intervals. Resume application immediately after harvest and continue through leaf drop.	FDAAFAN

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations	
Blueberry (continued)			
Mummyberry Phomopsis twig blight	2-4 lb/A [use 20-250 gal/A] (4.0 lb/gal FlC) (80% WP - granular size)	Delayed dormant and foliar applications. Begin applications at early green tip stage and repeat at 1 to 2 week intervals throughout petal fall.	FIBMMCB FBAEPBU
Anthracnose fruit rot	2-4 lb/A [use 20-250 gal/A] (4.0 lb/gal FlC) (80% WP - granular size)	Foliar application. Begin applications at full bloom and repeat at 10 to 20 day intervals.	FAAAGAN
Cherry (sweet)		2 ppm No preharvest interval through 1.6 pounds per 100 gallons.	/05002AA
Brown rot blossom blight	0.8-1.6 lb/ 100 gal (80% WP)	Use limited to California and Oregon. Delayed dormant and foliar application. Use sufficient spray per acre depending on tree size to provide thorough coverage. Apply at prebloom, bloom and petal fall.	FBADMCB
Cherry (sour)		50 ppm No preharvest interval through 9.0 pounds per acre.	/05002AA
Cherry leaf spot (coccomyces)	0.4-1.0 lb/ 100 gal (80% WP) (80% WP - granular size)	Foliar application. Use sufficient spray per acre depending on the tree size, to provide thorough coverage. Begin applications at petal fall and repeat at 10 day intervals for 3 to 4 applications, then make a final application to the foliage after harvest.	FMBCCDJ

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitation	
Cherry (sour) (continued)		Use limited to Monmorency variety - to be mechanically harvested.	
Brown rot blossom blight	1.0 lb/100 gal (4 lb/gal FlC) (80% WP - granular size)	Foliar application. Use sufficient spray per acre, depending on the tree size, to provide thorough coverage. Begin applications at popcorn stage of blossom development. During periods of wet weather repeat application at 2 to 4 day intervals through petal fall.	FBADMCB
Brown rot fruit rot	1.0 lb/100 gal (4 lb/gal FLC) (80% WP - granular size)	Foliar application. Apply during wet weather or when conditions are favorable for disease development. Begin at petal fall or when leaves first unfold and repeat at 10 day interval. Do not exceed 4 applications.	FIALMCB
Cherry leaf spot (Coccomyces)	0.5-1.0 lb/ 100 gal (4 lb/gal FlC)	(a) seasonal program and post harvest control. Foliar application. Use sufficient spray per acre for thorough coverage. Begin application at petal fall or when leaves unfold and repeat at approximately 10 day intervals for 3 to 4 applications. Make one application after harvest. Use the higher rate during periods of wet weather or when conditions are favorable for disease development.	FMBCCDJ
	3 lb/100 gal [up to 300 gal/A] (4 lb/gal FlC)	(b) Reduced application program. Foliar application. Use maximum gallonage on mature trees. Make single application at petal fall or when leaves unfold for control through harvest.	

CAPTAFOL

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Corn (field)		N.F.	/28006AA
Damping off and seed rot	0.47 oz/bu or 0.875 oz/100 lb (70% WP)	Seed treatment. Apply as a water slurry.	FKAIQBB
Cotton		N.F.	/28007AA
(Acid delinted seed) Damping-off and seed rot	0.094 lb/ 100 lb seed (4 lb/gal FlC)	Seed treatment. For use in slurry treaters. Do not allow to stand overnight. Clean out equipment thoroughly between treating operations. Shake, roll or agitate container to improve uniformity.	FKAIQBB
(Machine delinted seed) Damping-off and seed rot	0.141 lb/100 lb seed (4 lb/gal FlC)	Seed treatment. For use in slurry treaters. Do not allow to stand overnight. Clean out equipment thoroughly between treating operations. Shake, roll or agitate container to improve uniformity.	FKAIQBB
Cranberry		8 ppm 50 day preharvest interval through 5.0 pounds per acre.	/01010AA
Fruit Rot	3-5 lb/100-300 gal/A (4 lb/gal FlC) (80% WP - granular size)	Foliar applications. Vary the rate according to the plant size. Apply at bloom and repeat at 10 to 14 day intervals for a total of 3 applications each year.	FIBFQBB
Cucumber		2 ppm No preharvest interval through 3.5 pounds per acre.	/10010AA

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Cucumber (continued)			
Alternaria leaf blight Anthracnose Downy mildew Gummy stem blight blight Scab	1.20-1.6 lb /A [Use 50-150 gal/A] (4 lb/gal FlC) (80% WP)	Foliar application. Apply when first tree leaves appear and continue at weekly intervals. Adjust rate of water per acre used to obtain thorough coverage.	FBATAAX FAAACDP FFABPEA FBACMCO FFAJCCV
Fruit rot (Belly rot)	3.25 lb/A [use 30-50 gal/A] (4 lb/gal FlC)	Use limited to Southeastern United States. Foliar and soil application. Make at single application after last cultivation or when vines begin to run. Direct spray to the bed soil.	FIACRAM
Grapefruit Lemon Lime Orange (including Murcott Honey and Temple cultivars) Tangerines		0.5 ppm Do not apply to any citrus when mature fruits are on the tree. Do not concentrate more than 2 times when tank mixing with Boron formulations. Do not tank mix with Boron or technical manganese formulations for aerial application. Mixing captafol and spray oils will cause phytotoxicity.	/02002AA /02004AA /02005AA /02006AA /02008AA
Melanose Scab Citrus rust mite*	3.2-4.0 lb/100 gal [use up to 2000 gal/A] (4 lb/gal FlC)	Use limited to Florida on fruit for processing. Foliar application. Apply up to 2000 gallons per acre, depending on the size of tree or or equivalent amount per acre as a concentrate spray. Use the higher rate on groves with a history of severe scab.	FIBLDAP FEAJEAH ILAJBCA
	12 lb/10 gal/A (4 lb/gal FlC)	Foliar applicaton by air. Use a suitable spreader-sticker. Do not concentrate more than 1:1 with water, or use 10 gallons finished spray per acre. Apply as a delayed dormant spray after crop harvest and crop hedging or pruning. Apply only in groves equipped with overhead irrigation since rainfall or overhead irrigation during dry seasons is required to redistribute the captafol to newly developed leaf and fruit growth.	

*"rust mite" control is an acaricidal (insecticidal) claim, not fungicidal.

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Grapefruit Orange Tangerine		0.5 ppm Do not apply to any citrus when mature fruits are on the trees. Captafol can cause a rind spotting when applied to young citrus fruit. Do not concentrate sprays above 6 times the ground concentration when tank mixing with Boron formulations. Do not mix captafol and spray oils. Do not tank mix with Boron for aerial application.	/02002AA /02006AA /02008AA
Melanose Scab	0.8-1.0 lb/100 gal [use up to 2000 gal/A] (4 lb/gal FlC)	Use limited to Florida to fruit for processing. Foliar application. Use maximum gallonage for larger trees or equivalent amount per acre as a concentrate spray. Use higher rate on groves with a history of severe melanose.	FIBLDAP FEAJEAH
	5.0 lb/10 gal/A (4 lb/gal FlC)	Foliar application by air. Use on orange or temple oranges for processing and on temple oranges for fresh market. Apply as a post-bloom spray (from 2/3 petal fall to 3 weeks after petal fall).	
Macadamia Nuts		0.1 ppm No preharvest interval through 11.2 pounds per acre.	/03007AA
Raceme (Blossom blight) (Botrytis)	1.6 lb/100 gal [use 700 gal/A] or 1.6 lb/10 gal [use 70 gal/A] for mist blower application (80% WP) or 11 lb/700 gal/A or	Use limited to Hawaii. Delayed dormant & foliar application. Apply at weekly intervals during the bloom period of February and March. Apply twice weekly during periods of severe infection. Follow small gallonage recommendation for mist applications.	FBADBAW

CAPTAFOL

Site and Pest	Dosage and Formulations	Tolerance, Use, Limitations	
Macadamia Nuts (continued)			
	11 lb/70 gal/A for mist blower application (4 lb/gal flC)		
Melons (cantaloupe, honey dew, muskmelon & others)		5 ppm No preharvest interval through 2.5 pounds per acre.	/10001AA
Alternaria leaf blight Downy mildew Anthracnose Gummy stem blight	1.25-2.5 lb/A [use 100 to 150 gal/A] (80% WP) (4 lb/gal FlC)	Foliar application. Apply gallonage level as required to obtain through coverage. Begin application when first tree leaves appear and repeat at weekly intervals.	FBATAAX FFABPEA FAAACDP FBAQMCO
Nectarine		2 ppm	/05003AA
Coryneum blight Peach leaf curl	6.4-12.8 lb/A (80% WP) or 1.5 fl. oz. 27% FlC/gal (27% FlC)	Dormant application. Use up to 400 gallons water per acre or sufficient water to cover. Apply lower rate in the fall before rains begin and repeat in late winter prior to bud swell; or apply the higher rate as a single treatment after leaves have dropped prior to fall rains.	FBAZCEL FEAGTAB
Onion		0.1 ppm No preharvest interval through 1.25 pounds per acre.	/14011AA
Purple blotch Downy mildew Botrytis (blight)	1.25 lb/100 gal/A (4 lb/gal	Foliar application. Begin applications when disease first appears and repeat at 7-10 day intervals.	FCAEAAX FFABPAU FBAABAW

CAPTAFOL

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Peach		30 ppm	/05004AA
Coryneum blight Peach leaf curl	6.4-12.8 lb/A (80% WP) or 1.5 fl. oz. 27% FlC/gal (27% FlC)	Dormant application. Use up to 400 gallons water per acre or sufficient water to cover. Apply lower rate in the fall before rains begin and repeat in late winter prior to bud swell; or apply the higher rate as a single treatment after leaves have dropped prior to fall rains.	FBAZCEL FEAGTAB
Peanut		2 ppm (in hulls) 0.05 ppm (hulls removed) 14 day preharvest interval through 1.5 pounds per acre. Do not graze treated area or feed treated vines or hay to livestock. Do not hog down treated areas.	/28015AA
Cercospora leafspot	1.5 lb/A [use 10-60 gal/A ground equip. or 5-10 gal/ A aerial] (4 lb/gal FlC)	Foliar application. Apply when disease first appears (25-45 days post-plant). Repeat at 10-14 day intervals to maintain control.	FMBCCBM
Damping off and seed rot (Aspergillus) Damping off and seed rot (Rhizopus) Damping off and seed rot	0.11-0.2 lb /100 lb seed (35% D) (60% D) (65% D)	Seed treatment. Apply with commerical treating machine for uniform seed treatment coverage. May be formulated with 2,6-dichloro-4-nitroaniline.	FKAIACG FKAIRAQ FKAIQBB
Pineapple		0.1 ppm No preharvest interval through 31.25 pounds per acre.	/06013AA

CAPTAFOL

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Pineapple (continued)			
Pineapple heart rot	1.25 lb/10 gal mixture (4 lb/gal FlC) (80% WP)	Dip treatment. Dip slips immediately before planting using 100 to 250 gallons dip per acre.	FIBIPCN
	8 lb/400 gal/ A (4 lb/gal FlC)	Soil application. Apply first application immediately after planting; repeat at monthly intervals for a maximum of 8 applications.	
Plum **Prune**		2 ppm No preharvest interval through 1.6 pounds per 100 gallons.	/05005AA /05006AA
Brown rot blossom blight	0.75-1.6 lb 100 gal (80 WP)	Use limited to California and Oregon. Delayed dormant and foliar application. Use sufficient spray per acre depending on tree size to provide thorough coverage. Apply at prebloom, bloom and petal fall.	FBADMCB
Potato		0.5 ppm No preharvest interval through 1.6 pounds per acre.	/14013AA
Early blight Late blight	0.75-1.6 lb/A (4 lb/gal FlC) (80% WP) (25% WP)	Foliar application. Apply in sufficient water to cover. Begin when plants are 6 inches high and continue at 5 to 10 day intervals. Under severe disease condition use higher listed dosage and shorter spray intervals. May be formulated with captan.	FBAMAAX FBASPCN
Rice		N.F.	/28072AA
Seed rot and seedling disease (Achlya) Seed rot and seedling disease (Pythium) Seed rot and seedling disease (Helminthosporum)	0.125-0.188 lb/100 lb seed (4 lb/gal FlC)	Seed treatment. Treat seeds prior to pre-soaking when planting in flooded fields.	FKAFADD FKAFPES FKAFHAM

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Sorghum (grain and forage)		N.F.	/28019AA
Damping-off and seed rot	2.1 oz/100 lb (70% WP)	Seed treatment. Apply as a water slurry.	FKAIQBB
Sweet Corn		0.1 ppm 5 day preharvest interval through 1.0 pound per acre. Use limited to Florida. For fresh vegetable use only. Do not feed treated forage to livestock or allow animals to graze treated area.	/15005AA
Northern corn leaf blight Southern corn leaf blight	0.38-1.0 lb/A (4 lb/gal FlC)	Foliar application by air. Use in 3 to 5 gallons as required for thorough coverage. When disease conditions are prevalent use 0.38 to 0.5 pounds per acre on a 2 day schedule to protect new growth. As a preventive or under light disease conditions use 0.75 to 1.0 pound on a 4 day schedule.	FBATSBP FBATCDM
Taro (wetland)		0.02 ppm 11 week preharvest interval through 1.5 pounds per acre. Use limited to Hawaii. Do not apply more than 36 pounds captafol per acre per year.	/14006AA
Phytophthora leaf blight	0.75-1.5 lb/100 gal/A (4 lb/gal FlC)	Folair application. Begin when infection is expected (normally 3 months after planting) and repeat at 7 to 14 day intervals until danger of infection is passed (normally 5 months after first application). Under very wet conditions, use the higher dosage or the shorter spray interval. Under dry conditions, treat at 14 to 21 day intervals.	FBATPCN

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Tomato		15.0 ppm No preharvest interval through 16 pounds per acre. Use limited to mechanically harvested tomatoes. Immature fruit may be spotted when captafol is combined with insecticides during periods of high temperature or drought stress.	/11005AA
Anthracnose Early blight Fruit rot Gray leaf mold (Stemphylium) Late blight Nailhead spot	1.2-2.5 lb/ [use 30-150 gal/A for ground equipment or 5-100 gal/A by air] (4 lb/gal FlC) (80% WP)	Apply when first fruits are well formed and repeat at 7 to 10 day intervals. When weather conditions favor disease development, use higher rate and begin application when plants are set in fields.	FAAACDP FBAMAAX FBASPCN FMAXSDG FMBFAAX FIBFQAB
Anthracnose fruit rot	8-16 lb/A (4 lb/gal FlC)	Foliar application. Apply as a single spray when the first fruits are formed; or use 4 to 8 pounds actual in two applications. Apply the first treatment when first fruits are formed followed by a second treatment 20 days later.	FAAACDP
Black mold (Alternaria alternata)	1-2 lb/A [use 30-200 gal/A by ground or 10 gal/A by air] (4 lb/gal FlC)	Use limited to California. Foliar application. Apply when first fruits are well formed and repeat at 7 to 10 day intervals.	FIBFAAX

Site and Pest	Dosage and Formulation(s)	Tolerance, Use, Limitations	
Watermelon		5.0 ppm No preharvest interval through 2.5 pounds per acre.	/10008AA
Anthracnose Downy mildew Gummy stem blight	1.2-2.5 lb/A [use in 50-150 gal/A] (4 lb/gal FlC) (80% WP)	Foliar application. Begin applications when plants start to vine and repeat at 5-10 day intervals as needed. Use lower gallonage for initial application and increase for thorough coverage depending upon plant size.	FAAACDP FFABPEA FBAQMCO
STRUCTURE, WOOD PRODUCTS AND WOOD COMMODITIES			
Wood Protection treatment by pressure			/640100AA
Surface mold	1-2 pints 39% EC/300 gal preservative solution. (39% EC)	Wood protection treatment by pressure. Add one pint of the formulation to 300 gallons ready to use wood preserving solution for pressure treatment of wood. (Wood preserving solutions of 0.5 to 6.0 percent concentration of copper-chrome arsenate or fluoride-chrome arsenate-phenol preservative in water are suitable for use. This gives the recommended minimum of 200 ppm active ingredient concentration.) Under extremely hot humid conditions, the concentration may be doubled to get the required control.	
AERIAL AND TANK MIX APPLICATIONS			
Aerial Application			9001500 AAAAAAA
	Refer to AGRICULTURAL CROPS	Peanuts, sweet corn, tomato	

EPA Index to Pesticide Chemicals

CAPTAFOL

Listing of Registered Pesticide Products by Formulation

97% technical chemical
captafol (081701)
000239-02230

35% dust
captafol (082701) plus 2,6-dichloro-4-nitroaniline (031301)
000239-02273

60% dust
captafol (081701) plus 2,6-dichloro-4-nitroaniline (031301)
000239-02407

65% dust
captafol (081701)
000239-02198

25% wettable powder
captafol (081701) plus captan (081301)
000239-02195

70% wettable powder
captafol (081701) plus methoxychlor (034001)
000239-02409

80% wettable powder
captafol (081701)
000239-01716 000239-02217

80% wettable powder (granular size)
captafol (081701)
000239-02495

39% emulsifiable concentrate
captafol (081701)
003008-00027

27% flowable concentrate
captafol (081701)
000239-02313

4 lb/gal flowable concentrate
captafol (081701)
000239-02211 000239-02369

CAPTAFOL

State Label Registration 9999999

CA Reg. No.
000239-04198

HI Reg. No.
000239-04168 037843-08576

NY Reg. No.
038655-10453

EPA Index to Pesticide Chemicals

CAPTAFOL

Auxiliary documentation: Summary of 24c registrations by Crop.

Site	Pest	Accession number
Citrus (bark treatment)	Foot rot (Phytophthora)	FL800038
Citrus (soil treatment)	Greasy spot (Mycosphaerella)	FL820033
Corn (seed treatment)	Seed rot and seedling blight (Pythium, Rhizoctonia, Rhizopus)	FL780064 ID800050
Peanuts (foliar treatment)	Leaf spot (Cercospora)	TX770010
Pineapple (foliar treatment)	Heart rot (Phytophthora)	HI770006
Pineapple (dip treatment)	Heart rot (Phytophthora)	HI770006
Potato (water treatment)	Early blight (Alternaria)	OR810083
" " "	" " "	WA780027
" " "	Early blight (Alternaria) Late blight (Phytophthora)	CO790018 MI800016 NE800016
Strawberry (nursery stock)	Anthracnose (Colletotrichum)	AR790002
Sugarcane (growth regulator) Not Fungicidal	stimulation of germination	FL760012
Tomato (soil treatment, greenhouse)	Fusarium crown and root rot	OH760002 NC760003
Watermelon (foliar treatment)	Anthracnose (Colletotrichum) Downy mildew (Pseudoperonospora) Gummy stem blight (Mycosphaerella)	TX780044